



Docket No.: SON-2313  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Satoshi Ikeda

Confirmation No.: 3283

Application No.: 10/052,736

Art Unit: 2133

Filed: January 23, 2002

Examiner: J. C. Kerveros

For: SEMICONDUCTOR TESTING APPARATUS  
AND METHOD

**APPELLANT'S BRIEF**

MS Appeal Brief - Patents  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

**INTRODUCTORY COMMENTS**

This is an Appeal Brief under 37 C.F.R. §41.37 appealing the final decision of the Examiner dated January 4, 2005. Each of the topics required by 37 C.F.R. §41.37 is presented herewith and is labeled appropriately.

This brief is in furtherance of the Final Office Action on January 4, 2005.

A Notice of Appeal has been filed in this case concurrent with the Appeal Brief.

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**I. REAL PARTY IN INTEREST**

Sony Corporation of Tokyo, Japan ("Sony") is the real party in interest of the present application. An assignment of all rights in the present application to Sony was executed by the inventor and recorded by the U.S. Patent and Trademark Office at reel 012531, frame 0679.

## **II. RELATED APPEALS AND INTERFERENCES**

There are no other appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

## **III. STATUS OF CLAIMS**

Claims 1-2 (canceled);

Claim 3 (rejected);

Claims 4-5 (canceled);

Claims 6-32 (rejected).

## **IV. STATUS OF AMENDMENTS**

Subsequent to the final rejection of January 4, 2005, an Amendment After Final Action (37 CFR Section 1.116) has been filed concurrent with the Appeal Brief for the purpose of amending the Abstract to the specification in the manner requested by the Examiner.

## **V. SUMMARY OF CLAIMED SUBJECT MATTER**

The present invention relates to an apparatus and a method for testing a semiconductor, and more particularly to those for testing a semiconductor device by first supplying an input signal of a test pattern to the semiconductor device and then comparing the output signal from the semiconductor device with a predetermined expected value.

Disclosed is a test pattern memory means 130 adapted to store a first test pattern, wherein the first test pattern is outputted from the test pattern memory means in response to an address specifying signal (specification at page 10, lines 10-15). The rate of output for the first test pattern is the test pattern cycle period (specification at page 10, lines 13-15).

The control means 110 is adapted to generate a timing signal and an address specifying signal (specification at page 9, lines 11-16). The duration of said test pattern cycle period can be varied (specification at page 9, lines 16-20). The rate of modification for the address specifying signal is the test pattern cycle period (specification at figures 2, 3A, 3B, 3C, and 4).

Test pattern generation means 120 is adapted to generate an input test pattern signal by combining the first test pattern with the timing signal (specification at page 10, lines 3-7). Moreover, semiconductor device under test 500 receives the input test pattern signal (specification at figure 1).

## **VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

The issues presented for consideration in this appeal are as follows:

Whether the Examiner erred in rejecting claim 3 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement.

Whether the Examiner erred in rejecting claim 3 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite.

Whether the Examiner erred in rejecting claims 3 and 6-32 under 35 U.S.C. §102 as allegedly being anticipated by U.S. Patent No. 6,314,536 to Kurosaki.

These issues will be discussed hereinbelow.

## **VII. ARGUMENT**

In the Final Office Action of January 4, 2005:

The Examiner erred in rejecting claim 3 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement.

The Examiner erred in rejecting claim 3 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite.

The Examiner erred in rejecting claims 3 and 6-32 under 35 U.S.C. §102 as allegedly being anticipated by Kurosaki.

For at least the following reasons, Appellant submits that these rejections are both technically and legally unsound and should therefore be reversed.

### **General issues**

The following objection is not the subject for the appeal, but a discussion of the objection is provided only for the purposes of completeness.

The Final Office Action includes an objection to the specification as lacking an enabling description, in reference to the limitation “the set information” recited in the independent claim 3.

This objection is traversed at least for the reasons provided hereinbelow with respect to the rejection of claim 3 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement.

Withdrawal of this objection and allowance of the claims is respectfully requested.

Claims 3 and 6-21 were rejected for the use of the term “adapted to”.



This objection is traversed at least for the following reasons.

The term “adapted to” has been previously found by the Examiner to be acceptable claim language. For example, the Examiner has found such claim language acceptable within claims 13 and 15 of U.S. Patent No. 6,809,528. The Examiner has found such claim language acceptable within claim 1 of U.S. Patent No. 6,791,339. The Examiner has also found such claim language acceptable within claim 29 of U.S. Patent No. 6,756,789. Many other examples of the Examiner finding the term “adapted to” as acceptable claim language are within the U.S. Patent collection. Respectfully, this objection is inconsistent with other actions taken by the Examiner. Clarification as to why the term “adapted to” is now deemed unacceptable is respectfully requested.

Withdrawal of this objection and allowance of the claims is respectfully requested.

#### **Grouping of claims**

Claims 3 and 6-32 are currently pending and finally rejected in this application, with claims 3, 6 and 22 being independent. For purposes of the issues presented by this appeal:

Claim 3 stands or falls alone.

Claims 6-7 and 9-10 stand or fall together.

Claim 8 stands or falls alone.

Claim 11 stands or falls alone.

Claim 12 stands or falls alone.

Claim 13 stands or falls alone.

Claim 14 stands or falls alone.

Claim 15 stands or falls alone.

Claim 16 stands or falls alone.

Claim 17 stands or falls alone.

Claim 18 stands or falls alone.

Claim 19 stands or falls alone.

Claim 20 stands or falls alone.

Claim 21 stands or falls alone.

Claim 22 stands or falls alone.

Claim 23 stands or falls alone.

Claim 24 stands or falls alone.

Claim 25 stands or falls alone.

Claim 26 stands or falls alone.

Claim 27 stands or falls alone.

Claim 28 stands or falls alone.

Claim 29 stands or falls alone.

Claim 30 stands or falls alone.

Claim 31 stands or falls alone.

Claim 32 stands or falls alone.

The arguments set forth in the following section provide reasons why these claims are considered patentable, 37 C.F.R. §41.37(c)(1)(vii).

**The Examiner erred in rejecting claim 3 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement.**

Claim 3 was rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement.

This rejection is traversed at least for the following reasons.

In response to this contention, please note that section 112 requires only an objective enablement; the invention needs to be sufficiently disclosed through illustrative examples or terminology to teach those of ordinary skill in the art how to make and how to use the invention as broadly as it is claimed. *In re Marzocchi*, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971). See also M.P.E.P. §§2164.01, 2164.04.

“A specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of Section 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support” (emphasis added). *Fiers v. Revel*, 984 F.2d 1164, 1172, 25 USPQ2d 1601, 1607 (Fed. Cir. 1993). See also M.P.E.P. §2164.04.

Assuming that sufficient reason for such doubt does exist, a rejection for failure to teach how to make and/or use will be proper on that basis; such a rejection can be overcome by suitable proofs indicating that the teaching contained in the specification is truly enabling. *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (1971).

“How the specification accomplishes this is not material. It is not necessary that the application describe the claim limitations exactly, but only so clearly that persons of ordinary

skill in the art will recognize from the disclosure that the [Applicant] invented [the claimed invention] (emphasis added). *In re Wertheim*, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976). “The applicant does not have to utilize any particular form of disclosure to describe the subject matter claimed.” *In re Alton*, 76 F.3d 1168, 1172, 37 USPQ2d 1578, 1581 (Fed. Cir. 1996).

The term “the set information” is fully supported within the specification as originally filed. For example:

The specification as originally filed at page 9, lines 16-20, provides that “as the control means 110 controls the timings to generate both the timing signal and the address specifying signal in conformity with the set information, the test pattern cycle period for any address can be varied.”

The specification as originally filed at page 9, lines 20-22, provides that “the set information is transferred to the semiconductor testing apparatus 100 prior to or during the test by some method.”

The specification as originally filed at page 9, lines 23 to page 10, line 2, provides that “in execution of the test, the control means 110 always refers to the latest set information to thereby control the timings to generate the timing signal and the address specifying signal.”

The specification as originally filed at page 11, lines 13-16, provides that “and set information for controlling the cycle period to execute the test pattern of each address is also set prior to start of the test.”

The specification as originally filed at page 11, lines 17-22, provides that “upon start of the test, the control means 110 forms an operation reference signal to operate the test pattern, and generates a timing signal to produce a test pattern signal in conformity with the set information, and further generates an address specifying signal per cycle period for the test pattern memory means 130.”

The specification as originally filed at page 12, lines 17-21, provides that “in this manner, as the control means 110 controls the timings to generate the timing signal and the address specifying signal in conformity with the set information, it becomes possible to freely set the test pattern cycle period of any desired address.”

The specification as originally filed at page 13, lines 12-18, provides that “in this case, the cycle period rate of the entire test pattern is set to a value (RATE 1) lower than the maximum operation frequency and, in conformity with the set information, the rate of the specific subject address only, i.e., the (N+3)-th cycle, is raised to a higher value (RATE 2).”

The specification as originally filed at page 13, line 24 to page 14, line 3, provides that “and the cycle frequency rate of the specific address can be successively narrowed by changing the set information, hence realizing confirmation of the maximum operation frequency in the relevant portion.”

The specification as originally filed at page 19, line 19 to page 20, line 1, provides that “in the semiconductor testing apparatus of the present invention, as described hereinabove, a test pattern for a specified address is outputted at a timing corresponding to set information, in such a manner that the test pattern is supplied to the semiconductor device, which is being tested, at the timing that conforms with the predetermined set information, whereby a test pattern signal is generated on the basis of such test pattern.”

The specification as originally filed at page 20, lines 1-4, provides that “as a result, the timing to generate the test pattern of the desired address is controlled in conformity with the set information, hence generating a desired test period.”

The Final Office Action contends that the specification lacks an enabling description with respect to the term “the set information” found within the claims (Office Action at page 4). The Final Office Action further contends that even though numerous examples have been cited, “the set information” is not defined either in the specification or by the Applicant’s arguments (Office Action at page 7).

In response, *it is incumbent upon the Patent Office*, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (1971).

At least for the reasons provided hereinabove, claim 3 complies with the enablement requirement of 35 U.S.C. §112, first paragraph.

Withdrawal of this rejection and allowance of the claims is respectfully requested.

*The Examiner erred in rejecting claim 3 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite.*

Claim 3 was rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite.

This rejection is traversed at least for the following reasons.

*The Final Office Action contends that the term “the set information” found within claim 3 lacks an antecedent basis* (Office Action at page 4).

In response to this contention, the term “the set information” is, itself, the first occurrence and need not require any additional antecedent basis. Usage of the definite article “the” is acceptable claim language in certain instances when presenting a first occurrence of a term.

Withdrawal of this rejection and allowance of the claims is respectfully requested.

*The Final Office Action contends that the term “the set information” found within claim 3 is a relative term* (Office Action at page 4).

In response to this contention, the Final Office Action has not shown that the term “the set information” found within claim 3 is a term of degree. See M.P.E.P. §2173.05(b).

Withdrawal of this rejection and allowance of the claims is respectfully requested.

*The Final Office Action contends that the phrase “such a manner” found within claim 3 is indefinite (Office Action at page 4).*

The Final Office Action refers to M.P.E.P. §2173.05(c). In response, the examples found within M.P.E.P. §2173.05(c) of claim language which have been held to be indefinite are fact specific and should not be applied as *per se* rules. In this regard, the language found within filed claim 3 of “in such a manner” has not been shown within M.P.E.P. §2173.05(c) to reach the definition of indefiniteness within the meaning of 35 U.S.C. §112, second paragraph.

The Final Office Action contends that the phrase “such a manner” is equivalent to the phrase “such as” (Office Action at page 8).

In response to this contention, the Final Office Action attempts to recast the express language found within the claims. Such a reconstruction is merely an attempt to redefine the invention in a manner different than from what is set forth within the claims. Such reconstruction is without authority under Title 35 U.S.C., Title 37 C.F.R., the M.P.E.P. and relevant case law; such reconstruction is therefore deemed unusual and improper.

Moreover, the phrase “such a manner” has been previously found by the Examiner to be acceptable claim language. For example, the Examiner has found such claim language acceptable within claim 4 of U.S. Patent No. 6,807,644. The Examiner has found such claim language acceptable within claim 1 of U.S. Patent No. 6,727,723. The Examiner also has found such claim language acceptable within claims 6 and 7 of U.S. Patent No. 6,522,153. Many other examples of the Examiner finding the term “such a manner” as acceptable claim language are within the U.S. Patent collection. Respectfully, this rejection is inconsistent with other actions taken by the Examiner. Clarification as to why the term “such a manner” is now deemed unacceptable is respectfully requested.

Withdrawal of this rejection and allowance of the claims is respectfully requested.

**The Examiner erred in rejecting claims 3 and 6-32 under 35 U.S.C. §102 as allegedly being anticipated by Kurosaki.**

Claims 3 and 6-32 were rejected under 35 U.S.C. §102 as allegedly being anticipated by U.S. Patent No. 6,314,536 to Kurosaki.

This rejection is traversed at least for the following reasons.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

**Claim 3**

Claim 3 is drawn to a semiconductor testing apparatus wherein an input signal of a test pattern is supplied to a semiconductor device, and an output signal obtained from said semiconductor device is compared with a prescribed expected value to conduct a test, said apparatus comprising:

test pattern memory means adapted for storing test pattern data of the test pattern, managing the test pattern data in accordance with addresses, and outputting the test pattern specified by any address;

test pattern generation means for generating a test pattern signal on the basis of the test pattern outputted from said test pattern memory means; and

control means for controlling said test pattern memory means and said test pattern generation means in such a manner that the test pattern signal based on the test pattern data of a desired address can be generated at a predetermined timing conforming to the set information,



wherein said control means controls the timing of generation of the test pattern in such a manner that the cycle period rate to execute the test pattern of the desired address becomes a cycle period narrower than a predetermined rate.

Kurosaki arguably teaches a memory testing apparatus having pattern generator 2 that generates a test pattern signal S1 applied to a device to be tested MUT 3 (column 6, lines 14-18), and a system controller 6.

The Final Office Action contends that Kurosaki teaches the pattern generator 2 as the test pattern generation means, and that the pattern generator 2 generates a test pattern signal S1 on the basis of the expected value pattern signal S2 from the test pattern memory means (Office Action at page 5). Yet, the Final Office Action fails to show where within Kurosaki that the feature of *the expected value pattern signal S2 from the test pattern memory means* is to be found.

In this regard, please note that the Final Office Action identifies element S2 of Kurosaki as both the test pattern memory means (S2) and the test pattern data (Office Action at page 5). In this regard, the Final Office Action lacks clarity.

The Final Office Action additionally asserts the pattern generator 2 of Kurosaki as including test pattern generation means for generating a test pattern signal S1, while simultaneously asserting the presence of the test pattern generation means (S1). Element S1 of Kurosaki has been applied in this manner for the alleged test pattern signal S1 and for the alleged test pattern generation means and for the test pattern signal S1 itself.

The Final Office Action contends that Kurosaki teaches the system controller 6 as the control means (Office Action at pages 5-6).

However, Kurosaki fails to disclose, teach or suggest the system controller 6 controlling the pattern generator 2 in such a manner that the cycle period rate to execute the test pattern S1 of the desired address becomes a cycle period narrower than a predetermined rate.

The Final Office Action contends that Kurosaki discloses the system controller 6 controls the timing of generation of the test pattern and varies the cycle period to execute the test pattern of the desired address (Office Action at page 9).

In response to this contention, Kurosaki arguably teaches that the reference clock supplied to the system controller 6 is given as *a test period signal TI for defining one test period or cycle* in the memory testing apparatus 1 (Kurosaki at column 1, lines 43-47).

The Final Office Action contends that the system controller 6 varies the cycle period by controlling the burst address producing circuit 8, which is capable of producing two burst address signals in one test period at twice the pulse repetition rate of the test period signal TI (Office Action at page 9).

In response to this contention, figures 2E and 3D of Kurosaki depict the test period signal TI as having a fixed cycle period. As a result, Kurosaki arguably teaches that the test period or cycle for the test period signal TI is fixed.

Furthermore, figure 5D of Kurosaki arguably teaches that the memory under test 3 produces two burst address signals in one internal clock period  $T_t$  such as ADR0 and ADR1 in the first internal clock period, and ADR2 and ADR3 in the second internal clock period (Kurosaki at column 3, 44-48). However, Kurosaki fails to disclose, teach or suggest the pattern generator 2 producing the two burst address signals. For example, in the case that the memory under test 3 operates in burst mode, an address signal which is added to the test pattern signal S1 and is applied to the memory under test 3 from the pattern generator 2 *is only one burst leading address signal* (also called the first address signal) which indicates an address of the leading or head data (the first data) in the burst, and burst address signals indicating addresses of *the second and subsequent data in the burst are automatically produced internally of the memory under test 3* in synchronism with the rising edge and the falling edge of an internal clock in the memory under test 3 (Kurosaki at column 2, lines 49-59).

Yet, Kurosaki fails to disclose, teach or suggest the system controller 6 as controlling the timing of generation of the test pattern in such a manner that the cycle period rate to execute

the test pattern of the desired address becomes a cycle period narrower than a predetermined rate.

Further note that the system controller 9 of Kurosaki arguably teaches the presence of an adder 11 for summing up the output of the address hold circuit 9 and the output of the counter 10 to produce a burst address signal (Kurosaki at column 7, lines 22-27).

But Kurosaki fails to disclose, teach or suggest the adder 11 as controlling the timing of generation of the test pattern in such a manner that the cycle period rate to execute the test pattern of the desired address becomes a cycle period narrower than a predetermined rate.

Kurosaki arguably teaches that in the case that a memory under test 3 operates in burst mode and/or adopts double data rate system, the first multiplexer 16 and the second multiplexer 12 select their input terminals "b" by a select signal supplied from the system controller 6 respectively (Kurosaki at column 7, lines 36-39). If a memory under test 3 operates in burst mode and does not adopt double data rate system, only the second multiplexer 12 selects its input terminal "b" by a select signal supplied from the system controller 6, and the first multiplexer 12 remains in the state of selecting its input terminal "a" (Kurosaki at column 7, lines 47-53). Further, in the case that a memory under test does not operate in burst mode, the second multiplexer 12 selects its input terminal "a" by a select signal supplied from the system controller 6 " (Kurosaki at column 9, lines 5-8).

Nevertheless, Kurosaki fails to disclose, teach or suggest the system controller 6 as controlling the timing of generation of the test pattern S1.

The Final Office Action contends that the system controller 6 varies the cycle period by controlling the burst address producing circuit 8, which is capable of producing two burst address signals in one test period at twice the pulse repetition rate of the test period signal TI (Office Action at page 9). But even if this contention is supported by the teaching of Kurosaki, the Final Office Action has failed to show that the system controller 6 controls the timing of generation of the test pattern S1.

A relationship between the system controller 6 and the timing of the test pattern S1 has been established neither within the Final Office Action nor within Kurosaki.

**Claims 6, 7, 9, 10**

Claim 6 and the claims dependent thereon include the features of:

control means adapted to generate a timing signal and an address specifying signal, said timing signal having a test pattern cycle period, the duration of said test pattern cycle period being variable, the rate of modification for said address specifying signal being said test pattern cycle period;

test pattern memory means adapted to store a first test pattern, said first test pattern being outputted from said test pattern memory means in response to said address specifying signal, the rate of output for said first test pattern being said test pattern cycle period; and

test pattern generation means adapted to generate an input test pattern signal by combining said first test pattern with said timing signal, a semiconductor device under test receiving said input test pattern signal.

In addition to the arguments provided hereinabove with respect to claim 3, Kurosaki fails to disclose, teach or suggest test pattern generation means adapted to generate an input test pattern signal by combining the first test pattern with the timing signal, a semiconductor device under test receiving the input test pattern signal. The Final Office Action fails to show where within Kurosaki that this feature is to be found.

**Claim 8**

The rejection of claim 8 is traversed for the reasons provided hereinabove with respect to claim 6, and for the following reasons.

Within claim 8, said control means is adapted to vary said duration of said test pattern cycle period.

However, the Kurosaki fails to show that the system controller 6 is adapted to vary the duration of the test pattern cycle period. Specifically, Kurosaki arguably teaches that the reference clock is given to the burst address producing circuit 8 as *a test period signal TI* for defining one test period or cycle in the memory testing apparatus 1 (Kurosaki at column 6, lines 48-51). In addition, figures 2E, 3D, and 5A of Kurosaki fail to show a variance in the test period signal TI.

#### **Claim 11**

The rejection of claim 11 is traversed for the reasons provided hereinabove with respect to claim 6, and for the following reasons.

Claim 11 includes said control means receiving set information to generate said timing signal and said address specifying signal, said set information establishing said duration of said test pattern cycle period.

Specifically, Kurosaki arguably teaches that the reference clock is given to the burst address producing circuit 8 as *a test period signal TI* for defining one test period or cycle in the memory testing apparatus 1 (Kurosaki at column 6, lines 48-51).

However, the Kurosaki fails to show that the system controller 6 receives set information to generate the timing signal TI. Instead, a timing generator 7 supplies a reference clock to the pattern generator 2 and the system controller 6 respectively (Kurosaki at column 6, lines 11-13).

In addition, Kurosaki fails to disclose, teach or suggest the use of set information to generate the address specifying signal.

Moreover, Kurosaki fails to disclose, teach or suggest set information that establishes the duration of the test pattern cycle period.

### **Claim 12**

The rejection of claim 12 is traversed for the reasons provided hereinabove with respect to claim 11, and for the following reasons.

Within claim 12 said control means controls the timing of generation of said first test pattern on the basis of said set information.

However, Kurosaki fails to disclose, teach or suggest the system controller 6 as controlling the timing of generation of a test pattern. Instead, the pattern generator 2 of Kurosaki arguably generates, in response to the reference clock supplied thereto from the timing generator 7, an address signal, a test signal of a predetermined pattern (a test pattern signal) S1 and a control signal which are to be supplied to an IC memory to be tested or under test 3 (commonly called MUT) (Kurosaki at column 6, lines 19-25).

In addition, Kurosaki fails to disclose, teach or suggest the system controller 6 as controlling the timing of generation of a test pattern on the basis of set information.

### **Claim 13**

The rejection of claim 13 is traversed for the reasons provided hereinabove with respect to claim 11, and for the following reasons.

Within claim 13, said test pattern cycle period is narrowed by varying said set information. However, figures 2E, 3D, and 5A of Kurosaki fail to show a variance in the test period signal TI.

**Claim 14**

The rejection of claim 14 is traversed for the reasons provided hereinabove with respect to claim 11, and for the following reasons.

Within claim 14, said test pattern cycle period is widened by varying said set information. However, figures 2E, 3D, and 5A of Kurosaki fail to show a variance in the test period signal TI.

**Claim 15**

The rejection of claim 15 is traversed for the reasons provided hereinabove with respect to claim 6, and for the following reasons.

Within claim 15, said test pattern memory means stores a plurality of test patterns, said plurality of test patterns being outputted from said test pattern memory means in response to said address specifying signal, the rate of output for said plurality of test patterns being said test pattern cycle period.

While Kurosaki arguably teaches that the pattern generator 2 generates a test signal of *a predetermined pattern* (a test pattern signal) S1 (Kurosaki at column 6, lines 14-18), Kurosaki fails to disclose, teach or suggest test pattern memory means that stores a plurality of test patterns.

**Claim 16**

The rejection of claim 16 is traversed for the reasons provided hereinabove with respect to claim 15, and for the following reasons.

Within claim 16, said duration of said test pattern cycle period only for said first test pattern is narrowed. However, figures 2E, 3D, and 5A of Kurosaki fail to show a variance in the test period signal TI.

### **Claim 17**

The rejection of claim 17 is traversed for the reasons provided hereinabove with respect to claim 15, and for the following reasons.

Within claim 17, said duration of said test pattern cycle period for said first test pattern and for said plurality of test patterns is narrowed. However, figures 2E, 3D, and 5A of Kurosaki fail to show a variance in the test period signal TI.

### **Claim 18**

The rejection of claim 18 is traversed for the reasons provided hereinabove with respect to claim 15, and for the following reasons.

Within claim 18, said duration of said test pattern cycle period for said plurality of test patterns is narrowed successively from the top pattern address throughout the entire test pattern in order. However, figures 2E, 3D, and 5A of Kurosaki fail to show a variance in the test period signal TI.

### **Claim 19**

The rejection of claim 19 is traversed for the reasons provided hereinabove with respect to claim 15, and for the following reasons.



Within claim 19, said duration of said test pattern cycle period only for said first test pattern is widened. However, figures 2E, 3D, and 5A of Kurosaki fail to show a variance in the test period signal TI.

#### **Claim 20**

The rejection of claim 20 is traversed for the reasons provided hereinabove with respect to claim 15, and for the following reasons.

Within claim 20, said duration of said test pattern cycle period for said first test pattern and for said plurality of test patterns is widened. However, figures 2E, 3D, and 5A of Kurosaki fail to show a variance in the test period signal TI.

#### **Claim 21**

The rejection of claim 21 is traversed for the reasons provided hereinabove with respect to claim 15, and for the following reasons.

Within claim 21, said duration of said test pattern cycle period for said plurality of test patterns is widened successively from the top pattern address throughout the entire test pattern in order. However, figures 2E, 3D, and 5A of Kurosaki fail to show a variance in the test period signal TI.

#### **Claim 22**

Claim 22 and the claims dependent thereon include the steps of:

generating a timing signal having a test pattern cycle period;

varying the duration of said test pattern cycle period;

generating an address specifying signal, the rate of modification for said address specifying signal being said test pattern cycle period;

storing a first test pattern within test pattern memory means;

outputting said first test pattern from within test pattern memory means in response to said address specifying signal, the rate of output for said first test pattern being said test pattern cycle period;

combining said first test pattern with said timing signal to generate an input test pattern signal, a semiconductor device under test receiving said input test pattern signal; and

comparing an output test pattern signal from said semiconductor device under test with said first test pattern.

In addition to the arguments provided hereinabove with respect to claim 3, Kurosaki fails to disclose, teach or suggest the step of combining the first test pattern with the timing signal to generate an input test pattern signal, a semiconductor device under test receiving the input test pattern signal. The Final Office Action fails to show where within Kurosaki that this step is to be found.

### **Claim 23**

The rejection of claim 23 is traversed for the reasons provided hereinabove with respect to claim 22, and for the following reasons.

Claim 23 includes the additional steps of receiving set information to generate said timing signal and said address specifying signal; and using said set information to establish said duration of said test pattern cycle period.

However, Kurosaki fails to disclose teach or suggest the step of receiving set information to generate the timing signal and the address specifying signal.

While Kurosaki arguably teaches the generation of a test period signal TI (Kurosaki at column 3, lines 28-29), Kurosaki fails to disclose, teach or suggest using set information to establish the duration of the test pattern cycle period.

#### **Claim 24**

The rejection of claim 24 is traversed for the reasons provided hereinabove with respect to claim 23, and for the following reasons.

Within claim 24, said test pattern cycle period is narrowed by varying said set information. However, figures 2E, 3D, and 5A of Kurosaki fail to show a variance in the test period signal TI.

#### **Claim 25**

The rejection of claim 25 is traversed for the reasons provided hereinabove with respect to claim 23, and for the following reasons.

Within claim 25, said test pattern cycle period is widened by varying said set information. However, figures 2E, 3D, and 5A of Kurosaki fail to show a variance in the test period signal TI.

#### **Claim 26**

The rejection of claim 26 is traversed for the reasons provided hereinabove with respect to claim 22, and for the following reasons.

Within claim 26, said test pattern memory means stores a plurality of test patterns, said plurality of test patterns being outputted from said test pattern memory means in response to said address specifying signal, the rate of output for said plurality of test patterns being said test pattern cycle period.

While Kurosaki arguably teaches that the pattern generator 2 generates a test signal of a *predetermined pattern* (a test pattern signal) S1 (Kurosaki at column 6, lines 14-18), Kurosaki fails to disclose, teach or suggest test pattern memory means that stores a plurality of test patterns.

#### **Claim 27**

The rejection of claim 27 is traversed for the reasons provided hereinabove with respect to claim 22, and for the following reasons.

Within claim 27, said duration of said test pattern cycle period only for said first test pattern is narrowed. However, figures 2E, 3D, and 5A of Kurosaki fail to show a variance in the test period signal TI.

Moreover, Kurosaki fails to teach a treatment only for the first test pattern.

#### **Claim 28**

The rejection of claim 28 is traversed for the reasons provided hereinabove with respect to claim 22, and for the following reasons.

Within claim 28, said duration of said test pattern cycle period for said first test pattern and for said plurality of test patterns is narrowed. However, figures 2E, 3D, and 5A of Kurosaki fail to show a variance in the test period signal TI.

Moreover, Kurosaki fails to teach a treatment only for the first test pattern.

While Kurosaki arguably teaches that the pattern generator 2 generates a test signal of *a predetermined pattern* (a test pattern signal) S1 (Kurosaki at column 6, lines 14-18), Kurosaki fails to disclose, teach or suggest test pattern memory means that stores a plurality of test patterns.

#### **Claim 29**

The rejection of claim 29 is traversed for the reasons provided hereinabove with respect to claim 22, and for the following reasons.

Within claim 29, said duration of said test pattern cycle period for said plurality of test patterns is narrowed successively from the top pattern address throughout the entire test pattern in order. However, figures 2E, 3D, and 5A of Kurosaki fail to show a variance in the test period signal TI.

Moreover, while Kurosaki arguably teaches that the pattern generator 2 generates a test signal of *a predetermined pattern* (a test pattern signal) S1 (Kurosaki at column 6, lines 14-18), Kurosaki fails to disclose, teach or suggest test pattern memory means that stores a plurality of test patterns.

#### **Claim 30**

The rejection of claim 30 is traversed for the reasons provided hereinabove with respect to claim 22, and for the following reasons.

Within claim 30, said duration of said test pattern cycle period only for said first test pattern is widened. However, figures 2E, 3D, and 5A of Kurosaki fail to show a variance in the test period signal TI.

Moreover, Kurosaki fails to teach a treatment only for the first test pattern.

**Claim 31**

The rejection of claim 31 is traversed for the reasons provided hereinabove with respect to claim 22, and for the following reasons.

Within claim 31, said duration of said test pattern cycle period for said first test pattern and for said plurality of test patterns is widened. However, figures 2E, 3D, and 5A of Kurosaki fail to show a variance in the test period signal TI.

Moreover, while Kurosaki arguably teaches that the pattern generator 2 generates a test signal of *a predetermined pattern* (a test pattern signal) S1 (Kurosaki at column 6, lines 14-18), Kurosaki fails to disclose, teach or suggest test pattern memory means that stores a plurality of test patterns.

**Claim 32**

The rejection of claim 32 is traversed for the reasons provided hereinabove with respect to claim 22, and for the following reasons.

Within claim 32, said duration of said test pattern cycle period for said plurality of test patterns is widened successively from the top pattern address throughout the entire test pattern in order.

Yet, figures 2E, 3D, and 5A of Kurosaki fail to show a variance in the test period signal TI.

Moreover, while Kurosaki arguably teaches that the pattern generator 2 generates a test signal of *a predetermined pattern* (a test pattern signal) S1 (Kurosaki at column 6, lines 14-18), Kurosaki fails to disclose, teach or suggest test pattern memory means that stores a plurality of test patterns.

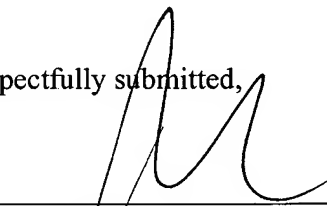
In addition, Kurosaki fails to disclose, teach or suggest the widening of a test pattern.

**Conclusion**

The claims are considered allowable for the same reasons discussed above, as well as for the additional features they recite. Reversal of the Examiner's decision is respectfully requested.

Dated: March 30, 2005

Respectfully submitted,



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**CLAIMS APPENDIX**

1-2. (canceled)

3. (previously presented) A semiconductor testing apparatus wherein an input signal of a test pattern is supplied to a semiconductor device, and an output signal obtained from said semiconductor device is compared with a prescribed expected value to conduct a test, said apparatus comprising:

test pattern memory means adapted for storing test pattern data of the test pattern, managing the test pattern data in accordance with addresses, and outputting the test pattern specified by any address;

test pattern generation means for generating a test pattern signal on the basis of the test pattern outputted from said test pattern memory means; and

control means for controlling said test pattern memory means and said test pattern generation means in such a manner that the test pattern signal based on the test pattern data of a desired address can be generated at a predetermined timing conforming to the set information,

wherein said control means controls the timing of generation of the test pattern in such a manner that the cycle period rate to execute the test pattern of the desired address becomes a cycle period narrower than a predetermined rate.

4-5. (canceled)

6. (previously presented) A semiconductor testing apparatus comprising:



control means adapted to generate a timing signal and an address specifying signal, said timing signal having a test pattern cycle period, the duration of said test pattern cycle period being variable, the rate of modification for said address specifying signal being said test pattern cycle period;

test pattern memory means adapted to store a first test pattern, said first test pattern being outputted from said test pattern memory means in response to said address specifying signal, the rate of output for said first test pattern being said test pattern cycle period; and

test pattern generation means adapted to generate an input test pattern signal by combining said first test pattern with said timing signal, a semiconductor device under test receiving said input test pattern signal.

7. (previously presented) The semiconductor testing apparatus according to claim 6, further comprising:

decision means adapted to detect a failure within said semiconductor device by comparing an output test pattern signal received from said semiconductor device under test with said first test pattern.

8. (previously presented) The semiconductor testing apparatus according to claim 6, wherein said control means is adapted to vary said duration of said test pattern cycle period.

9. (previously presented) The semiconductor testing apparatus according to claim 6, wherein said first test pattern is located at an address within said test pattern memory means.

10. (previously presented) The semiconductor testing apparatus according to claim 6, wherein said semiconductor device is tested during said test pattern cycle period.

11. (previously presented) The semiconductor testing apparatus according to claim 6, wherein said control means receiving set information to generate said timing signal and said address specifying signal, said set information establishing said duration of said test pattern cycle period.

12. (previously presented) The semiconductor testing apparatus according to claim 11, wherein said control means controls the timing of generation of said first test pattern on the basis of said set information.

13. (previously presented) The semiconductor testing apparatus according to claim 11, wherein said test pattern cycle period is narrowed by varying said set information.

14. (previously presented) The semiconductor testing apparatus according to claim 11, wherein said test pattern cycle period is widened by varying said set information.

15. (previously presented) The semiconductor testing apparatus according to claim 6, wherein said test pattern memory means stores a plurality of test patterns, said plurality of test patterns being outputted from said test pattern memory means in response to said address specifying signal, the rate of output for said plurality of test patterns being said test pattern cycle period.

16. (previously presented) The semiconductor testing apparatus according to claim 15, wherein said duration of said test pattern cycle period only for said first test pattern is narrowed.

17. (previously presented) The semiconductor testing apparatus according to claim 15, wherein said duration of said test pattern cycle period for said first test pattern and for said plurality of test patterns is narrowed.

18. (previously presented) The semiconductor testing apparatus according to claim 15, wherein said duration of said test pattern cycle period for said plurality of test patterns is narrowed successively from the top pattern address throughout the entire test pattern in order.

19. (previously presented) The semiconductor testing apparatus according to claim 15, wherein said duration of said test pattern cycle period only for said first test pattern is widened.

20. (previously presented) The semiconductor testing apparatus according to claim 15, wherein said duration of said test pattern cycle period for said first test pattern and for said plurality of test patterns is widened.

21. (previously presented) The semiconductor testing apparatus according to claim 15, wherein said duration of said test pattern cycle period for said plurality of test patterns is widened successively from the top pattern address throughout the entire test pattern in order.

22. (previously presented) A semiconductor testing method for conducting a test of a semiconductor device comprising the steps of:

generating a timing signal having a test pattern cycle period;

varying the duration of said test pattern cycle period;

generating an address specifying signal, the rate of modification for said address specifying signal being said test pattern cycle period;

storing a first test pattern within test pattern memory means;

outputting said first test pattern from within test pattern memory means in response to said address specifying signal, the rate of output for said first test pattern being said test pattern cycle period;

combining said first test pattern with said timing signal to generate an input test pattern signal, a semiconductor device under test receiving said input test pattern signal; and

comparing an output test pattern signal from said semiconductor device under test with said first test pattern.

23. (previously presented) The semiconductor testing method according to claim 22, further comprising the steps of:

receiving set information to generate said timing signal and said address specifying signal; and

using said set information to establish said duration of said test pattern cycle period.

24. (previously presented) The semiconductor testing method according to claim 23, wherein said test pattern cycle period is narrowed by varying said set information.

25. (previously presented) The semiconductor testing method according to claim 23, wherein said test pattern cycle period is widened by varying said set information.

26. (previously presented) The semiconductor testing method according to claim 22, wherein said test pattern memory means stores a plurality of test patterns, said plurality of test patterns being outputted from said test pattern memory means in response to said address specifying signal, the rate of output for said plurality of test patterns being said test pattern cycle period.

27. (previously presented) The semiconductor testing method according to claim 22, wherein said duration of said test pattern cycle period only for said first test pattern is narrowed.

28. (previously presented) The semiconductor testing method according to claim 22, wherein said duration of said test pattern cycle period for said first test pattern and for said plurality of test patterns is narrowed.

29. (previously presented) The semiconductor testing method according to claim 22, wherein said duration of said test pattern cycle period for said plurality of test patterns is narrowed successively from the top pattern address throughout the entire test pattern in order.

30. (previously presented) The semiconductor testing method according to claim 22, wherein said duration of said test pattern cycle period only for said first test pattern is widened.

31. (previously presented) The semiconductor testing method according to claim 22, wherein said duration of said test pattern cycle period for said first test pattern and for said plurality of test patterns is widened.

32. (previously presented) The semiconductor testing method according to claim 22, wherein said duration of said test pattern cycle period for said plurality of test patterns is widened successively from the top pattern address throughout the entire test pattern in order.

**EVIDENCE APPENDIX**

1. Manual of Patent Examining Procedure, Original Eighth Edition, August 2001, Latest Revision May 2004, pages 2100-184 to 2100-211.
2. *In re Alton*, 76 F.3d 1168, 37 USPQ2d 1578 (Fed. Cir. 1996).
3. *Fiers v. Revel*, 984 F.2d 1164, 25 USPQ2d 1601 (Fed. Cir. 1993).
4. *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 2 USPQ2d 1051 (Fed. Cir. 1987).
5. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976).
6. *In re Marzocchi*, 439 F.2d 220, 169 USPQ 367 (CCPA 1971).
7. U.S. Patent No. 6,809,528 to Stormbom et al.
8. U.S. Patent No. 6,807,644 to Reis et al.
9. U.S. Patent No. 6,791,339 to Licini et al.
10. U.S. Patent No. 6,756,789 to Parker et al.
11. U.S. Patent No. 6,727,723 to Shimizu et al.
12. U.S. Patent No. 6,522,153 to Mueller et al.

# **Manual of PATENT EXAMINING PROCEDURE**

Original Eighth Edition, August 2001

Latest Revision May 2004



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Third Edition, November 1961  
Fourth Edition, June 1979  
Fifth Edition, August 1983  
Sixth Edition, January 1995  
Seventh Edition, July 1998  
Eighth Edition, August 2001  
Revision 1, February 2003  
Revision 2, May 2004

### 2163.07(a) Inherent Function, Theory, or Advantage

By disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it. The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter. *In re Reynolds*, 443 F.2d 384, 170 USPQ 94 (CCPA 1971); *In re Smythe*, 480 F.2d 1376, 178 USPQ 279 (CCPA 1973). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted).

### 2163.07(b) Incorporation by Reference [R-1]

Instead of repeating some information contained in another document, an application may attempt to incorporate the content of another document or part thereof by reference to the document in the text of the specification. The information incorporated is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed. Replacing the identified material incorporated by reference with the actual text is not new matter. See MPEP § 608.01(p) for Office policy regarding incorporation by reference. >See MPEP § 2181 for the impact of incorporation by reference on the determination of whether applicant has complied with the requirements of 35 U.S.C. 112, second paragraph when 35 U.S.C. 112, sixth paragraph is invoked.<

### 2164 The Enablement Requirement [R-2]

The enablement requirement refers to the requirement of 35 U.S.C. 112, first paragraph that the speci-

fication describe how to make and how to use the invention. The invention that one skilled in the art must be enabled to make and use is that defined by the claim(s) of the particular application or patent.

The purpose of the requirement that the specification describe the invention in such terms that one skilled in the art can make and use the claimed invention is to ensure that the invention is communicated to the interested public in a meaningful way. The information contained in the disclosure of an application must be sufficient to inform those skilled in the relevant art how to both make and use the claimed invention. >However, to comply with 35 U.S.C. 112, first paragraph, it is not necessary to "enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect." *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1338, 68 USPQ2d 1940, 1944 (Fed. Cir. 2003) (an invention directed to a general system to improve the cleaning process for semiconductor wafers was enabled by a disclosure showing improvements in the overall system).< Detailed procedures for making and using the invention may not be necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention. A patent claim is invalid if it is not supported by an enabling disclosure.

The enablement requirement of 35 U.S.C. 112, first paragraph, is separate and distinct from the description requirement. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116-17 (Fed. Cir. 1991) ("the purpose of the 'written description' requirement is broader than to merely explain how to 'make and use' "). See also MPEP § 2161. Therefore, the fact that an additional limitation to a claim may lack descriptive support in the disclosure as originally filed does not necessarily mean that the limitation is also not enabled. In other words, the statement of a new limitation in and of itself may enable one skilled in the art to make and use the claim containing that limitation even though that limitation may not be described in the original disclosure. Consequently, such limitations must be analyzed for both enablement and description using their separate and distinct criteria.

Furthermore, when the subject matter is not in the specification portion of the application as filed but is

in the claims, the limitation in and of itself may enable one skilled in the art to make and use the claim containing the limitation. When claimed subject matter is only presented in the claims and not in the specification portion of the application, the specification should be objected to for lacking the requisite support for the claimed subject matter using Form Paragraph 7.44. See MPEP § 2163.06. This is an objection to the specification only and enablement issues should be treated separately.

### 2164.01 Test of Enablement

Any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Accordingly, even though the statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). See also *United States v. Teletronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) ("The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation."). A patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984). Determining enablement is a question of law based on underlying factual findings.

*In re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991); *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984).

### UNDUE EXPERIMENTATION

The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), *aff'd. sub nom.*, *Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985). See also *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976).

### 2164.01(a) Undue Experimentation Factors

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

- (A) The breadth of the claims;
- (B) The nature of the invention;
- (C) The state of the prior art;
- (D) The level of one of ordinary skill;
- (E) The level of predictability in the art;
- (F) The amount of direction provided by the inventor;
- (G) The existence of working examples; and
- (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

*In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (reversing the PTO's determination that claims directed to methods for detection of hepatitis B surface antigens did not satisfy the enablement requirement). In *Wands*, the court noted that there was no disagreement as to the facts, but merely a disagreement as to the interpretation of the data and the conclusion to be made from the facts. *In re Wands*, 858 F.2d at 736-40, 8 USPQ2d at 1403-07. The Court

held that the specification was enabling with respect to the claims at issue and found that “there was considerable direction and guidance” in the specification; there was “a high level of skill in the art at the time the application was filed;” and “all of the methods needed to practice the invention were well known.” 858 F.2d at 740, 8 USPQ2d at 1406. After considering all the factors related to the enablement issue, the court concluded that “it would not require undue experimentation to obtain antibodies needed to practice the claimed invention.” *Id.*, 8 USPQ2d at 1407.

It is improper to conclude that a disclosure is not enabling based on an analysis of only one of the above factors while ignoring one or more of the others. The examiner’s analysis must consider all the evidence related to each of these factors, and any conclusion of nonenablement must be based on the evidence as a whole. 858 F.2d at 737, 740, 8 USPQ2d at 1404, 1407.

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

The determination that “undue experimentation” would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the above noted factual considerations. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. These factual considerations are discussed more fully in MPEP § 2164.08 (scope or breadth of the claims), § 2164.05(a) (nature of the invention and state of the prior art), § 2164.05(b) (level of one of ordinary skill), § 2164.03 (level of predictability in the art and amount of direction provided by the inventor), § 2164.02 (the existence of working examples) and § 2164.06 (quantity of experimentation needed to make or use the invention based on the content of the disclosure).

### 2164.01(b) How to Make the Claimed Invention

As long as the specification discloses at least one method for making and using the claimed invention

that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Failure to disclose other methods by which the claimed invention may be made does not render a claim invalid under 35 U.S.C. 112. *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1533, 3 USPQ2d 1737, 1743 (Fed. Cir.), *cert. denied*, 484 U.S. 954 (1987).

Naturally, for unstable and transitory chemical intermediates, the “how to make” requirement does not require that the applicant teach how to make the claimed product in stable, permanent or isolatable form. *In re Breslow*, 616 F.2d 516, 521, 205 USPQ 221, 226 (CCPA 1980).

A key issue that can arise when determining whether the specification is enabling is whether the starting materials or apparatus necessary to make the invention are available. In the biotechnical area, this is often true when the product or process requires a particular strain of microorganism and when the microorganism is available only after extensive screening.

The Court in *In re Ghiron*, 442 F.2d 985, 991, 169 USPQ 723, 727 (CCPA 1971), made clear that if the practice of a method requires a particular apparatus, the application must provide a sufficient disclosure of the apparatus if the apparatus is not readily available. The same can be said if certain chemicals are required to make a compound or practice a chemical process. *In re Howarth*, 654 F.2d 103, 105, 210 USPQ 689, 691 (CCPA 1981).

### 2164.01(c) How to Use the Claimed Invention

If a statement of utility in the specification contains within it a connotation of how to use, and/or the art recognizes that standard modes of administration are known and contemplated, 35 U.S.C. 112 is satisfied. *In re Johnson*, 282 F.2d 370, 373, 127 USPQ 216, 219 (CCPA 1960); *In re Hitchings*, 342 F.2d 80, 87, 144 USPQ 637, 643 (CCPA 1965). See also *In re Brana*, 51 F.2d 1560, 1566, 34 USPQ2d 1437, 1441 (Fed. Cir. 1993).

For example, it is not necessary to specify the dosage or method of use if it is known to one skilled in the art that such information could be obtained without undue experimentation. If one skilled in the art,

based on knowledge of compounds having similar physiological or biological activity, would be able to discern an appropriate dosage or method of use without undue experimentation, this would be sufficient to satisfy 35 U.S.C. 112, first paragraph. The applicant need not demonstrate that the invention is completely safe. See also MPEP § 2107.01 and § 2107.03.

When a compound or composition claim is limited by a particular use, enablement of that claim should be evaluated based on that limitation. See *In re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991) (claiming a chimeric gene capable of being expressed in any cyanobacterium and thus defining the claimed gene by its use).

In contrast, when a compound or composition claim is not limited by a recited use, any enabled use that would reasonably correlate with the entire scope of that claim is sufficient to preclude a rejection for nonenablement based on how to use. If multiple uses for claimed compounds or compositions are disclosed in the application, then an enablement rejection must include an explanation, sufficiently supported by the evidence, why the specification fails to enable each disclosed use. In other words, if any use is enabled when multiple uses are disclosed, the application is enabling for the claimed invention.

### 2164.02 Working Example

Compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed. An example may be “working” or “prophetic.” A working example is based on work actually performed. A prophetic example describes an embodiment of the invention based on predicted results rather than work actually conducted or results actually achieved.

An applicant need not have actually reduced the invention to practice prior to filing. In *Gould v. Quigg*, 822 F.2d 1074, 1078, 3 USPQ 2d 1302, 1304 (Fed. Cir. 1987), as of Gould’s filing date, no person had built a light amplifier or measured a population inversion in a gas discharge. The Court held that “The mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it.” 822 F.2d at 1078, 3 USPQ2d at 1304 (quoting *In re Chilowsky*, 229 F.2d 457, 461, 108 USPQ 321, 325 (CCPA 1956)).

The specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. *In re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970).

Lack of a working example, however, is a factor to be considered, especially in a case involving an unpredictable and undeveloped art. But because only an enabling disclosure is required, applicant need not describe all actual embodiments.

### NONE OR ONE WORKING EXAMPLE

When considering the factors relating to a determination of non-enablement, if all the other factors point toward enablement, then the absence of working examples will not by itself render the invention non-enabled. In other words, lack of working examples or lack of evidence that the claimed invention works as described should never be the sole reason for rejecting the claimed invention on the grounds of lack of enablement. A single working example in the specification for a claimed invention is enough to preclude a rejection which states that nothing is enabled since at least that embodiment would be enabled. However, a rejection stating that enablement is limited to a particular scope may be appropriate.

The presence of only one working example should never be the sole reason for rejecting claims as being broader than the enabling disclosure, even though it is a factor to be considered along with all the other factors. To make a valid rejection, one must evaluate all the facts and evidence and state why one would not expect to be able to extrapolate that one example across the entire scope of the claims.

### CORRELATION: *IN VITRO/IN VIVO*

The issue of “correlation” is related to the issue of the presence or absence of working examples. “Correlation” as used herein refers to the relationship between *in vitro* or *in vivo* animal model assays and a disclosed or a claimed method of use. An *in vitro* or *in vivo* animal model example in the specification, in effect, constitutes a “working example” if that example “correlates” with a disclosed or claimed method invention. If there is no correlation, then the examples do not constitute “working examples.” In this regard, the issue of “correlation” is also dependent on

the state of the prior art. In other words, if the art is such that a particular model is recognized as correlating to a specific condition, then it should be accepted as correlating unless the examiner has evidence that the model does not correlate. Even with such evidence, the examiner must weigh the evidence for and against correlation and decide whether one skilled in the art would accept the model as reasonably correlating to the condition. *In re Brana*, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) (reversing the PTO decision based on finding that *in vitro* data did not support *in vivo* applications).

Since the initial burden is on the examiner to give reasons for the lack of enablement, the examiner must also give reasons for a conclusion of lack of correlation for an *in vitro* or *in vivo* animal model example. A rigorous or an invariable exact correlation is not required, as stated in *Cross v. Iizuka*, 753 F.2d 1040, 1050, 224 USPQ 739, 747 (Fed. Cir. 1985):

[B]ased upon the relevant evidence as a whole, there is a reasonable correlation between the disclosed *in vitro* utility and an *in vivo* activity, and therefore a rigorous correlation is not necessary where the disclosure of pharmacological activity is reasonable based upon the probative evidence. (Citations omitted.)

## WORKING EXAMPLES AND A CLAIMED GENUS

For a claimed genus, representative examples together with a statement applicable to the genus as a whole will ordinarily be sufficient if one skilled in the art (in view of level of skill, state of the art and the information in the specification) would expect the claimed genus could be used in that manner without undue experimentation. Proof of enablement will be required for other members of the claimed genus only where adequate reasons are advanced by the examiner to establish that a person skilled in the art could not use the genus as a whole without undue experimentation.

### 2164.03 Relationship of Predictability of the Art and the Enablement Requirement [R-2]

The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art. *In re Fisher*, 427 F.2d 833, 839,

166 USPQ 18, 24 (CCPA 1970). The “amount of guidance or direction” refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling. >See, e.g., *Chiron Corp. v. Genentech Inc.*, 363 F.3d 1247, 1254, 70 USPQ2d 1321, 1326 (Fed. Cir. 2004) (“Nascent technology, however, must be enabled with a ‘specific and useful teaching.’ The law requires an enabling disclosure for nascent technology because a person of ordinary skill in the art has little or no knowledge independent from the patentee’s instruction. Thus, the public’s end of the bargain struck by the patent system is a full enabling disclosure of the claimed technology.” (citations omitted)).<

The “predictability or lack thereof” in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. If one skilled in the art can readily anticipate the effect of a change within the subject matter to which the claimed invention pertains, then there is predictability in the art. On the other hand, if one skilled in the art cannot readily anticipate the effect of a change within the subject matter to which that claimed invention pertains, then there is lack of predictability in the art. Accordingly, what is known in the art provides evidence as to the question of predictability. In particular, the court in *In re Marzocchi*, 439 F.2d 220, 223-24, 169 USPQ 367, 369-70 (CCPA 1971), stated:

[I]n the field of chemistry generally, there may be times when the well-known unpredictability of chemical reactions will alone be enough to create a reasonable doubt as to the accuracy of a particular broad statement put forward as enabling support for a claim. This will especially be the case where the statement is, on its face, contrary to generally accepted scientific principles. Most often, additional factors, such as the teachings in pertinent references, will be available to substantiate any doubts that the asserted scope of objective enablement is in fact commensurate with the scope of protection sought and to support any demands based thereon for proof. [Footnote omitted.]

The scope of the required enablement varies inversely with the degree of predictability involved, but even in unpredictable arts, a disclosure of every operable species is not required. A single embodiment may provide broad enablement in cases involving predictable factors, such as mechanical or electrical elements. *In re Vickers*, 141 F.2d 522, 526-27, 61 USPQ 122, 127 (CCPA 1944); *In re Cook*, 439 F.2d 730, 734, 169 USPQ 298, 301 (CCPA 1971). However, in applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. *In re Soll*, 97 F.2d 623, 624, 38 USPQ 189, 191 (CCPA 1938). In cases involving unpredictable factors, such as most chemical reactions and physiological activity, more may be required. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity). See also *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *In re Vaeck*, 947 F.2d 488, 496, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991). This is because it is not obvious from the disclosure of one species, what other species will work.

#### **2164.04 Burden on the Examiner Under \*the< Enablement Require- ment [R-1]**

Before any analysis of enablement can occur, it is necessary for the examiner to construe the claims. For terms that are not well-known in the art, or for terms that could have more than one meaning, it is necessary that the examiner select the definition that he/she intends to use when examining the application, based on his/her understanding of what applicant intends it to mean, and explicitly set forth the meaning of the term and the scope of the claim when writing an Office action. See *Genentech v. Wellcome Foundation*, 29 F.3d 1555, 1563-64, 31 USPQ2d 1161, 1167-68 (Fed. Cir. 1994).

In order to make a rejection, the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) (examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure). A specification disclosure which con-

tains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. Assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis. *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). As stated by the court, "it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure." 439 F.2d at 224, 169 USPQ at 370.

According to *In re Bowen*, 492 F.2d 859, 862-63, 181 USPQ 48, 51 (CCPA 1974), the minimal requirement is for the examiner to give reasons for the uncertainty of the enablement. This standard is applicable even when there is no evidence in the record of operability without undue experimentation beyond the disclosed embodiments. See also *In re Brana*, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) (citing *In re Bundy*, 642 F.2d 430, 433, 209 USPQ 48, 51 (CCPA 1981)) (discussed in MPEP § 2164.07 regarding the relationship of the enablement requirement to the utility requirement of 35 U.S.C. 101).

While the analysis and conclusion of a lack of enablement are based on the factors discussed in MPEP § 2164.01(a) and the evidence as a whole, it is not necessary to discuss each factor in the written enablement rejection. The language should focus on those factors, reasons, and evidence that lead the examiner to conclude that the specification fails to teach how to make and use the claimed invention without undue experimentation, or that the scope of any enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims. This can be done by making specific findings of fact, supported by the evidence, and then drawing conclusions based on these findings of fact.



For example, doubt may arise about enablement because information is missing about one or more essential parts or relationships between parts which one skilled in the art could not develop without undue experimentation. In such a case, the examiner should specifically identify what information is missing and why one skilled in the art could not supply the information without undue experimentation. See MPEP § 2164.06(a). References should be supplied if possible to support a *prima facie* case of lack of enablement, but are not always required. *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). However, specific technical reasons are always required.

In accordance with the principles of compact prosecution, if an enablement rejection is appropriate, the first Office action on the merits should present the best case with all the relevant reasons, issues, and evidence so that all such rejections can be withdrawn if applicant provides appropriate convincing arguments and/or evidence in rebuttal. Providing the best case in the first Office action will also allow the second Office action to be made final should applicant fail to provide appropriate convincing arguments and/or evidence. Citing new references and/or expanding arguments in a second Office action could prevent that Office action from being made final. The principles of compact prosecution also dictate that if an enablement rejection is appropriate and the examiner recognizes limitations that would render the claims enabled, the examiner should note such limitations to applicant as early in the prosecution as possible.

In other words, the examiner should always look for enabled, allowable subject matter and communicate to applicant what that subject matter is at the earliest point possible in the prosecution of the application.

### **2164.05 Determination of Enablement Based on Evidence as a Whole**

Once the examiner has weighed all the evidence and established a reasonable basis to question the enablement provided for the claimed invention, the burden falls on applicant to present persuasive arguments, supported by suitable proofs where necessary, that one skilled in the art would be able to make and use the claimed invention using the application as a guide. *In re Brandstadter*, 484 F.2d 1395, 1406-07,

179 USPQ 286, 294 (CCPA 1973). The evidence provided by applicant need not be conclusive but merely convincing to one skilled in the art.

Applicant may submit factual affidavits under 37 CFR 1.132 or cite references to show what one skilled in the art knew at the time of filing the application. A declaration or affidavit is, itself, evidence that must be considered. The weight to give a declaration or affidavit will depend upon the amount of factual evidence the declaration or affidavit contains to support the conclusion of enablement. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991) (“expert’s opinion on the ultimate legal conclusion must be supported by something more than a conclusory statement”); *cf. In re Alton*, 76 F.3d 1168, 1174, 37 USPQ2d 1578, 1583 (Fed. Cir. 1996) (declarations relating to the written description requirement should have been considered).

Applicant should be encouraged to provide any evidence to demonstrate that the disclosure enables the claimed invention. In chemical and biotechnical applications, evidence actually submitted to the FDA to obtain approval for clinical trials may be submitted. However, considerations made by the FDA for approving clinical trials are different from those made by the PTO in determining whether a claim is enabled. See *Scott v. Finney*, 34 F.3d 1058, 1063, 32 USPQ2d 1115, 1120 (Fed. Cir. 1994) (“Testing for full safety and effectiveness of a prosthetic device is more properly left to the [FDA].”). Once that evidence is submitted, it must be weighed with all other evidence according to the standards set forth above so as to reach a determination as to whether the disclosure enables the claimed invention.

To overcome a *prima facie* case of lack of enablement, applicant must demonstrate by argument and/or evidence that the disclosure, as filed, would have enabled the claimed invention for one skilled in the art at the time of filing. This does not preclude applicant from providing a declaration after the filing date which demonstrates that the claimed invention works. However, the examiner should carefully compare the steps, materials, and conditions used in the experiments of the declaration with those disclosed in the application to make sure that they are commensurate in scope; i.e., that the experiments used the guidance in the specification as filed and what was well known to one of skill in the art. Such a showing also must be



commensurate with the scope of the claimed invention, i.e., must bear a reasonable correlation to the scope of the claimed invention.

The examiner must then weigh all the evidence before him or her, including the specification and any new evidence supplied by applicant with the evidence and/or sound scientific reasoning previously presented in the rejection and decide whether the claimed invention is enabled. The examiner should **never** make the determination based on personal opinion. The determination should always be based on the weight of all the evidence.

### **2164.05(a) Specification Must Be Enabling as of the Filing Date [R-2]**

Whether the specification would have been enabling as of the filing date involves consideration of the nature of the invention, the state of the prior art, and the level of skill in the art. The initial inquiry is into the nature of the invention, i.e., the subject matter to which the claimed invention pertains. The nature of the invention becomes the backdrop to determine the state of the art and the level of skill possessed by one skilled in the art.

The state of the prior art is what one skilled in the art would have known, at the time the application was filed, about the subject matter to which the claimed invention pertains. The relative skill of those in the art refers to the skill of those in the art in relation to the subject matter to which the claimed invention pertains at the time the application was filed. See MPEP § 2164.05(b).

The state of the prior art provides evidence for the degree of predictability in the art and is related to the amount of direction or guidance needed in the specification as filed to meet the enablement requirement. The state of the prior art is also related to the need for working examples in the specification.

The state of the art for a given technology is not static in time. It is entirely possible that a disclosure filed on January 2, 1990, would not have been enabled. However, if the same disclosure had been filed on January 2, 1996, it might have enabled the claims. Therefore, the state of the prior art must be evaluated for each application based on its filing date.

35 U.S.C. 112 requires the specification to be enabling only to a person "skilled in the art to which it pertains, or with which it is most nearly connected."

In general, the pertinent art should be defined in terms of the problem to be solved rather than in terms of the technology area, industry, trade, etc. for which the invention is used.

The specification need not disclose what is well-known to those skilled in the art and preferably omits that which is well-known to those skilled and already available to the public. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Linde-mann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).

The state of the art existing at the filing date of the application is used to determine whether a particular disclosure is enabling as of the filing date. >*Chiron Corp. v. Genentech Inc.*, 363 F.3d 1247, 1254, 70 USPQ2d 1321, 1325-26 (Fed. Cir. 2004) ("a patent document cannot enable technology that arises after the date of application"). < Publications dated after the filing date providing information publicly first disclosed after the filing date generally cannot be used to show what was known at the time of filing. *In re Gunn*, 537 F.2d 1123, 1128, 190 USPQ 402,405-06 (CCPA 1976); *In re Budnick*, 537 F.2d 535, 538, 190 USPQ 422, 424 (CCPA 1976) (In general, if an applicant seeks to use a patent to prove the state of the art for the purpose of the enablement requirement, the patent must have an issue date earlier than the effective filing date of the application.). While a later dated publication cannot supplement an insufficient disclosure in a prior dated application to make it enabling, applicant can offer the testimony of an expert based on the publication as evidence of the level of skill in the art at the time the application was filed. *Gould v. Quigg*, 822 F.2d 1074, 1077, 3 USPQ2d 1302, 1304 (Fed. Cir. 1987).

In general, the examiner should not use post-filing date references to demonstrate that the patent is non-enabling. Exceptions to this rule could occur if a later-dated reference provides evidence of what one skilled in the art would have known on or before the effective filing date of the patent application. *In re Hogan*, 559 F.2d 595, 605, 194 USPQ 527, 537 (CCPA 1977). If individuals of skill in the art state that a particular invention is not possible years after the filing date,

that would be evidence that the disclosed invention was not possible at the time of filing and should be considered. In *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513-14 (Fed. Cir. 1993) an article published 5 years after the filing date of the application adequately supported the examiner's position that the physiological activity of certain viruses was sufficiently unpredictable so that a person skilled in the art would not have believed that the success with one virus and one animal could be extrapolated successfully to all viruses with all living organisms. Claims not directed to the specific virus and the specific animal were held nonenabled.

### 2164.05(b) Specification Must Be Enabling to Persons Skilled in the Art

The relative skill of those in the art refers to the skill of those in the art in relation to the subject matter to which the claimed invention pertains at the time the application was filed. Where different arts are involved in the invention, the specification is enabling if it enables persons skilled in each art to carry out the aspect of the invention applicable to their specialty. In *re Naquin*, 398 F.2d 863, 866, 158 USPQ 317, 319 (CCPA 1968).

When an invention, in its different aspects, involves distinct arts, the specification is enabling if it enables those skilled in each art, to carry out the aspect proper to their specialty. "If two distinct technologies are relevant to an invention, then the disclosure will be adequate if a person of ordinary skill in each of the two technologies could practice the invention from the disclosures." *Technicon Instruments Corp. v. Alpkem Corp.*, 664 F. Supp. 1558, 1578, 2 USPQ2d 1729, 1742 (D. Ore. 1986), *aff'd in part, vacated in part, rev'd in part*, 837 F. 2d 1097 (Fed. Cir. 1987) (unpublished opinion), appeal after remand, 866 F. 2d 417, 9 USPQ 2d 1540 (Fed. Cir. 1989). In *Ex parte Zech-nall*, 194 USPQ 461 (Bd. App. 1973), the Board stated "appellants' disclosure must be held sufficient if it would enable a person skilled in the electronic computer art, in cooperation with a person skilled in the fuel injection art, to make and use appellants' invention." 194 USPQ at 461.

### 2164.06 Quantity of Experimentation

The quantity of experimentation needed to be performed by one skilled in the art is only one factor

involved in determining whether "undue experimentation" is required to make and use the invention. "[A]n extended period of experimentation may not be undue if the skilled artisan is given sufficient direction or guidance." *In re Colianni*, 561 F.2d 220, 224, 195 USPQ 150, 153 (CCPA 1977). "The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (citing *In re Angstadt*, 537 F.2d 489, 502-04, 190 USPQ 214, 217-19 (CCPA 1976)). Time and expense are merely factors in this consideration and are not the controlling factors. *United States v. Teletronics Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988), *cert. denied*, 490 U.S. 1046 (1989).

In the chemical arts, the guidance and ease in carrying out an assay to achieve the claimed objectives may be an issue to be considered in determining the quantity of experimentation needed. For example, if a very difficult and time consuming assay is needed to identify a compound within the scope of a claim, then this great quantity of experimentation should be considered in the overall analysis. Time and difficulty of experiments are not determinative if they are merely routine. Quantity of examples is only one factor that must be considered before reaching the final conclusion that undue experimentation would be required. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404.

#### I. EXAMPLE OF REASONABLE EXPERIMENTATION

In *United States v. Teletronics, Inc.*, 857 F.2d 778, 8 USPQ2d 1217 (Fed. Cir. 1988), *cert. denied*, 490 U.S. 1046 (1989), the court reversed the findings of the district court for lack of clear and convincing proof that undue experimentation was needed. The court ruled that since one embodiment (stainless steel electrodes) and the method to determine dose/response was set forth in the specification, the specification was enabling. The question of time and expense of such studies, approximately \$50,000 and 6-12 months standing alone, failed to show undue experimentation.

## II. EXAMPLE OF UNREASONABLE EXPERIMENTATION

In *In re Ghiron*, 442 F.2d 985, 991-92, 169 USPQ 723, 727-28 (CCPA 1971), functional “block diagrams” were insufficient to enable a person skilled in the art to practice the claimed invention with only a reasonable degree of experimentation because the claimed invention required a “modification to prior art overlap computers,” and because “many of the components which appellants illustrate as rectangles in their drawing necessarily are themselves complex assemblages . . . . It is common knowledge that many months or years elapse from the announcement of a new computer by a manufacturer before the first prototype is available. This does not bespeak of a routine operation but of extensive experimentation and development work . . . .”

### 2164.06(a) Examples of \*>Enablement< Issues-Missing Information [R-1]

It is common that doubt arises about enablement because information is missing about one or more essential parts or relationships between parts which one skilled in the art could not develop without undue experimentation. In such a case, the examiner should specifically identify what information is missing and why the missing information is needed to provide enablement.

## I. ELECTRICAL AND MECHANICAL DEVICES OR PROCESSES

For example, a disclosure of an electrical circuit apparatus, depicted in the drawings by block diagrams with functional labels, was held to be nonenabling in *In re Gunn*, 537 F.2d 1123, 1129, 190 USPQ 402, 406 (CCPA 1976). There was no indication in the specification as to whether the parts represented by boxes were “off the shelf” or must be specifically constructed or modified for applicant’s system. Also there were no details in the specification of how the parts should be interconnected, timed and controlled so as to obtain the specific operations desired by the applicant. In *In re Donohue*, 550 F.2d 1269, 193 USPQ 136 (CCPA 1977), the lack of enablement was caused by lack of information in the specification about a single block labelled “LOGIC” in the drawings. See also

*Union Pacific Resources Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 57 USPQ2d 1293 (Fed. Cir. 2001) (Claims directed to a method of determining the location of a horizontal borehole in the earth failed to comply with enablement requirement of 35 U.S.C. 112 because certain computer programming details used to perform claimed method were not disclosed in the specification, and the record showed that a person of skill in art would not understand how to “compare” or “rescale” data as recited in the claims in order to perform the claimed method.).

In *In re Ghiron*, 442 F.2d 985, 169 USPQ 723 (CCPA 1971), involved a method of facilitating transfers from one subset of program instructions to another which required modification of prior art “overlap mode” computers. The Board rejected the claims on the basis, *inter alia*, that the disclosure was insufficient to satisfy the requirements of 35 U.S.C. 112, first paragraph and was affirmed. The Board focused on the fact that the drawings were “block diagrams, i.e., a group of rectangles representing the elements of the system, functionally labelled and interconnected by lines.” 442 F.2d at 991, 169 USPQ at 727. The specification did not particularly identify each of the elements represented by the blocks or the relationship therebetween, nor did it specify particular apparatus intended to carry out each function. The Board further questioned whether the selection and assembly of the required components could be carried out routinely by persons of ordinary skill in the art.

An adequate disclosure of a device may require details of how complex components are constructed and perform the desired function. The claim before the court in *In re Scarbrough*, 500 F.2d 560, 182 USPQ 298 (CCPA 1974) was directed to a system which comprised several component parts (e.g., computer, timing and control mechanism, A/D converter, etc.) only by generic name and overall ultimate function. The court concluded that there was not an enabling disclosure because the specification did not describe how “complex elements known to perform broadly recited functions in different systems would be adaptable for use in Appellant’s particular system with only a reasonable amount of experimentation” and that “an unreasonable amount of work would be required to arrive at the detailed relationships appellant says that he has solved.” 500 F.2d at 566, 182 USPQ at 302.

## II. MICROORGANISMS

Patent applications involving living biological products, such as microorganisms, as critical elements in the process of making the invention, present a unique question with regard to availability. The issue was raised in a case involving claims drawn to a fermentative method of producing two novel antibiotics using a specific microorganism and claims to the novel antibiotics so produced. *In re Argoudelis*, 434 F.2d 1390, 168 USPQ 99 (CCPA 1970). As stated by the court, “a unique aspect of using microorganisms as starting materials is that a sufficient description of how to obtain the microorganism from nature cannot be given.” 434 F.2d at 1392, 168 USPQ at 102. It was determined by the court that availability of the biological product via a public depository provided an acceptable means of meeting the written description and the enablement requirements of 35 U.S.C. 112, first paragraph.

To satisfy the enablement requirement a deposit must be made “prior to issue” but need not be made prior to filing the application. *In re Lundak*, 773 F.2d 1216, 1223, 227 USPQ 90, 95 (Fed. Cir. 1985).

The availability requirement of enablement must also be considered in light of the scope or breadth of the claim limitations. The Board of Appeals considered this issue in an application which claimed a fermentative method using microorganisms belonging to a species. Applicants had identified three novel individual strains of microorganisms that were related in such a way as to establish a new species of microorganism, a species being a broader classification than a strain. The three specific strains had been appropriately deposited. The issue focused on whether the specification enabled one skilled in the art to make any member of the species other than the three strains which had been deposited. The Board concluded that the verbal description of the species was inadequate to allow a skilled artisan to make any and all members of the claimed species. *Ex parte Jackson*, 217 USPQ 804, 806 (Bd. App. 1982).

See MPEP § 2402 - § 2411.03 for a detailed discussion of the deposit rules. See MPEP § 2411.01 for rejections under 35 U.S.C. 112 based on deposit issues.

## III. DRUG CASES

See MPEP § 2107 - § 2107.03 for a discussion of the utility requirement under 35 U.S.C. 112, first paragraph, in drug cases.

### 2164.06(b) Examples of Enablement Issues — Chemical Cases

The following summaries should not be relied on to support a case of lack of enablement without carefully reading the case.

#### SEVERAL DECISIONS RULING THAT THE DISCLOSURE WAS NONENABLING

(A) In *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 52 USPQ2d 1129 (Fed. Cir. 1999), the court held that claims in two patents directed to genetic antisense technology (which aims to control gene expression in a particular organism), were invalid because the breadth of enablement was not commensurate in scope with the claims. Both specifications disclosed applying antisense technology in regulating three genes in *E. coli*. Despite the limited disclosures, the specifications asserted that the “[t]he practices of this invention are generally applicable with respect to any organism containing genetic material which is capable of being expressed ... such as bacteria, yeast, and other cellular organisms.” The claims of the patents encompassed application of antisense methodology in a broad range of organisms. Ultimately, the court relied on the fact that (1) the amount of direction presented and the number of working examples provided in the specification were very narrow compared to the wide breadth of the claims at issue, (2) antisense gene technology was highly unpredictable, and (3) the amount of experimentation required to adapt the practice of creating antisense DNA from *E. coli* to other types of cells was quite high, especially in light of the record, which included notable examples of the inventor’s own failures to control the expression of other genes in *E. coli* and other types of cells. Thus, the teachings set forth in the specification provided no more than a “plan” or “invitation” for those of skill in the art to experiment using the technology in other types of cells.

(B) In *In re Wright*, 999 F.2d 1557, 27 USPQ2d 1510 (Fed. Cir. 1993), the 1983 application disclosed a vaccine against the RNA tumor virus known as Prague Avian Sarcoma Virus, a member of the Rous Associated Virus family. Using functional language, Wright claimed a vaccine “comprising an immunologically effective amount” of a viral expression product. *Id.*, at 1559, 27 USPQ2d at 1511. Rejected claims covered all RNA viruses as well as avian RNA viruses. The examiner provided a teaching that in 1988, a vaccine for another retrovirus (i.e., AIDS) remained an intractable problem. This evidence, along with evidence that the RNA viruses were a diverse and complicated genus, convinced the Federal Circuit that the invention was not enabled for either all retroviruses or even for avian retroviruses.

(C) In *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993), a 1985 application functionally claimed a method of producing protein in plant cells by expressing a foreign gene. The court stated: “[n]aturally, the specification must teach those of skill in the art ‘how to make and use the invention as broadly as it is claimed.’ ” *Id.* at 1050, 29 USPQ2d at 2013. Although protein expression in dicotyledonous plant cells was enabled, the claims covered any plant cell. The examiner provided evidence that even as late as 1987, use of the claimed method in monocot plant cells was not enabled. *Id.* at 1051, 29 USPQ2d at 2014.

(D) In *In re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991), the court found that several claims were not supported by an enabling disclosure “[t]aking into account the relatively incomplete understanding of the biology of cyanobacteria as of appellants’ filing date, as well as the limited disclosure by appellants of the particular cyanobacterial genera operative in the claimed invention....” The claims at issue were not limited to any particular genus or species of cyanobacteria and the specification mentioned nine genera and the working examples employed one species of cyanobacteria.

(E) In *In re Colianni*, 561 F.2d 220, 222-23, 195 USPQ 150, 152 (CCPA 1977), the court affirmed a rejection under 35 U.S.C. 112, first paragraph, because the specification, which was directed to a method of mending a fractured bone by applying “sufficient” ultrasonic energy to the bone, did not

define a “sufficient” dosage or teach one of ordinary skill how to select the appropriate intensity, frequency, or duration of the ultrasonic energy.

#### SEVERAL DECISIONS RULING THAT THE DISCLOSURE WAS ENABLING

(A) In *PPG Ind. v. Guardian Ind.*, 75 F.3d 1558, 1564, 37 USPQ2d 1618, 1623 (Fed. Cir. 1996), the court ruled that even though there was a software error in calculating the ultraviolet transmittance data for examples in the specification making it appear that the production of a cerium oxide-free glass that satisfied the transmittance limitation would be difficult, the specification indicated that such glass could be made. The specification was found to indicate how to minimize the cerium content while maintaining low ultraviolet transmittance.

(B) In *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988), the court reversed the rejection for lack of enablement under 35 U.S.C. 112, first paragraph, concluding that undue experimentation would not be required to practice the invention. The nature of monoclonal antibody technology is such that experiments first involve the entire attempt to make monoclonal hybridomas to determine which ones secrete antibody with the desired characteristics. The court found that the specification provided considerable direction and guidance on how to practice the claimed invention and presented working examples, that all of the methods needed to practice the invention were well known, and that there was a high level of skill in the art at the time the application was filed. Furthermore, the applicant carried out the entire procedure for making a monoclonal antibody against HBsAg three times and each time was successful in producing at least one antibody which fell within the scope of the claims.

(C) In *In re Bundy*, 642 F.2d 430, 434, 209 USPQ 48, 51-52 (CCPA 1981), the court ruled that appellant’s disclosure was sufficient to enable one skilled in the art to use the claimed analogs of naturally occurring prostaglandins even though the specification lacked any examples of specific dosages, because the specification taught that the novel prostaglandins had certain pharmacological properties and possessed activity similar to known E-type prostaglandins.

## **2164.07 Relationship of Enablement Requirement to Utility Requirement of 35 U.S.C. 101**

The requirement of 35 U.S.C. 112, first paragraph as to how to use the invention is different from the utility requirement of 35 U.S.C. 101. The requirement of 35 U.S.C. 101 is that some specific, substantial, and credible use be set forth for the invention. On the other hand, 35 U.S.C. 112, first paragraph requires an indication of how the use (required by 35 U.S.C. 101) can be carried out, i.e., how the invention can be used.

If an applicant has disclosed a specific and substantial utility for an invention and provided a credible basis supporting that utility, that fact alone does not provide a basis for concluding that the claims comply with all the requirements of 35 U.S.C. 112, first paragraph. For example, if an applicant has claimed a process of treating a certain disease condition with a certain compound and provided a credible basis for asserting that the compound is useful in that regard, but to actually practice the invention as claimed a person skilled in the relevant art would have to engage in an undue amount of experimentation, the claim may be defective under 35 U.S.C. 112, but not 35 U.S.C. 101. To avoid confusion during examination, any rejection under 35 U.S.C. 112, first paragraph, based on grounds other than “lack of utility” should be imposed separately from any rejection imposed due to “lack of utility” under 35 U.S.C. 101 and 35 U.S.C. 112, first paragraph.

### **I. WHEN UTILITY REQUIREMENT IS NOT SATISFIED**

#### **A. Not Useful or Operative**

If a claim fails to meet the utility requirement of 35 U.S.C. 101 because it is shown to be nonuseful or inoperative, then it necessarily fails to meet the how-to-use aspect of the enablement requirement of 35 U.S.C. 112, first paragraph. As noted in *In re Fouché*, 439 F.2d 1237, 169 USPQ 429 (CCPA 1971), if “compositions are in fact useless, appellant’s specification cannot have taught how to use them.” 439 F.2d at 1243, 169 USPQ at 434. The examiner should make both rejections (i.e., a rejection under 35 U.S.C. 112, first paragraph and a rejection under 35 U.S.C.

101) where the subject matter of a claim has been shown to be nonuseful or inoperative.

The 35 U.S.C. 112, first paragraph, rejection should indicate that because the invention as claimed does not have utility, a person skilled in the art would not be able to use the invention as claimed, and as such, the claim is defective under 35 U.S.C. 112, first paragraph. A 35 U.S.C. 112, first paragraph, rejection should not be imposed or maintained unless an appropriate basis exists for imposing a rejection under 35 U.S.C. 101. In other words, Office personnel should not impose a 35 U.S.C. 112, first paragraph, rejection grounded on a “lack of utility” basis unless a 35 U.S.C. 101 rejection is proper. In particular, the factual showing needed to impose a rejection under 35 U.S.C. 101 must be provided if a 35 U.S.C. 112, first paragraph, rejection is to be imposed on “lack of utility” grounds. See MPEP § 2107 - § 2107.03 for a more detailed discussion of the utility requirements of 35 U.S.C. 101 and 112, first paragraph.

#### **B. Burden on the Examiner**

When the examiner concludes that an application is describing an invention that is nonuseful, inoperative, or contradicts known scientific principles, the burden is on the examiner to provide a reasonable basis to support this conclusion. Rejections based on 35 U.S.C. 112, first paragraph and 35 U.S.C. 101 should be made.

#### **Examiner Has Initial Burden To Show That One of Ordinary Skill in the Art Would Reasonably Doubt the Asserted Utility**

The examiner has the initial burden of challenging an asserted utility. Only after the examiner has provided evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince one of ordinary skill in the art of the invention’s asserted utility. *In re Swartz*, 232 F.3d 862, 863, 56 USPQ2d 1703, 1704 (Fed. Cir. 2000); *In re Brana*, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) (citing *In re Bundy*, 642 F.2d 430, 433, 209 USPQ 48, 51 (CCPA 1981)).

### C. *Rebuttal by Applicant*

If a rejection under 35 U.S.C. 101 has been properly imposed, along with a corresponding rejection under 35 U.S.C. 112, first paragraph, the burden shifts to the applicant to rebut the *prima facie* showing. *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). There is no predetermined amount or character of evidence that must be provided by an applicant to support an asserted utility. Rather, the character and amount of evidence needed to support an asserted utility will vary depending on what is claimed (*Ex parte Ferguson*, 117 USPQ 229, 231 (Bd. App. 1957)), and whether the asserted utility appears to contravene established scientific principles and beliefs. *In re Gazave*, 379 F.2d 973, 978, 154 USPQ 92, 96 (CCPA 1967); *In re Chilowsky*, 229 F.2d 457, 462, 108 USPQ 321, 325 (CCPA 1956). Furthermore, the applicant does not have to provide evidence sufficient to establish that an asserted utility is true “beyond a reasonable doubt.” *In re Irons*, 340 F.2d 974, 978, 144 USPQ 351, 354 (CCPA 1965). Instead, evidence will be sufficient if, considered as a whole, it leads a person of ordinary skill in the art to conclude that the asserted utility is more likely than not true. See MPEP § 2107.02 for a more detailed discussion of consideration of a reply to a *prima facie* rejection for lack of utility and evaluation of evidence related to utility.

## II. WHEN UTILITY REQUIREMENT IS SATISFIED

In some instances, the use will be provided, but the skilled artisan will not know how to effect that use. In such a case, no rejection will be made under 35 U.S.C. 101, but a rejection will be made under 35 U.S.C. 112, first paragraph. As pointed out in *Mowry v. Whitney*, 81 U.S. (14 Wall.) 620 (1871), an invention may in fact have great utility, i.e., may be “a highly useful invention,” but the specification may still fail to “enable any person skilled in the art or science” to use the invention. 81 U.S. (14 Wall.) at 644.

### 2164.08 Enablement Commensurate in Scope With the Claims [R-2]

All questions of enablement are evaluated against the claimed subject matter. The focus of the examination inquiry is whether everything within the scope of

the claim is enabled. Accordingly, the first analytical step requires that the examiner determine exactly what subject matter is encompassed by the claims. >See, e.g., *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244, 68 USPQ2d 1280, 1287 (Fed. Cir. 2003)(When a range is claimed, there must be reasonable enablement of the scope of the range. Here, the claims at issue encompassed amounts of silicon as high as 10% by weight, however the specification included statements clearly and strongly warning that a silicon content above 0.5% by weight in an aluminum coating causes coating problems. Such statements indicate that higher amounts will not work in the claimed invention.)< The examiner should determine what each claim recites and what the subject matter is when the claim is considered as a whole, not when its parts are analyzed individually. No claim should be overlooked. With respect to dependent claims, 35 U.S.C. 112, fourth paragraph, should be followed. This paragraph states that “a claim in a dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers” and requires the dependent claim to further limit the subject matter claimed.

The Federal Circuit has repeatedly held that “the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without ‘undue experimentation’.” *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). Nevertheless, not everything necessary to practice the invention need be disclosed. In fact, what is well-known is best omitted. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). All that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art. Further the scope of enablement must only bear a “reasonable correlation” to the scope of the claims. See, e.g., *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

As concerns the breadth of a claim relevant to enablement, the only relevant concern should be whether the scope of enablement provided to one skilled in the art by the disclosure is commensurate with the scope of protection sought by the claims. >*AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244, 68 USPQ2d 1280, 1287 (Fed. Cir. 2003);< *In re Moore*, 439 F.2d 1232, 1236, 169 USPQ 236, 239 (CCPA 1971). See also *Plant Genetic Sys., N.V. v. DeKalb*



*Genetics Corp.*, 315 F.3d 1335, 1339, 65 USPQ2d 1452, 1455 (Fed. Cir. 2003) (alleged “pioneer status” of invention irrelevant to enablement determination).

The determination of the propriety of a rejection based upon the scope of a claim relative to the scope of the enablement involves two stages of inquiry. The first is to determine how broad the claim is with respect to the disclosure. The entire claim must be considered. The second inquiry is to determine if one skilled in the art is enabled to make and use the entire scope of the claimed invention without undue experimentation.

How a teaching is set forth, by specific example or broad terminology, is not important. *In re Marzocchi*, 439 F.2d 220, 223-24 169 USPQ 367, 370 (CCPA 1971). A rejection of a claim under 35 U.S.C. 112 as broader than the enabling disclosure is a first paragraph enablement rejection and not a second paragraph definiteness rejection. Claims are not rejected as broader than the enabling disclosure under 35 U.S.C. 112 for noninclusion of limitations dealing with factors which must be presumed to be within the level of ordinary skill in the art; the claims need not recite such factors where one of ordinary skill in the art to whom the specification and claims are directed would consider them obvious. *In re Skrivan*, 427 F.2d 801, 806, 166 USPQ 85, 88 (CCPA 1970). One does not look to the claims but to the specification to find out how to practice the claimed invention. *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1558, 220 USPQ 303, 316-17 (Fed. Cir. 1983); *In re Johnson*, 558 F.2d 1008, 1017, 194 USPQ 187, 195 (CCPA 1977). In *In re Goffe*, 542 F.2d 564, 567, 191 USPQ 429, 431 (CCPA 1976), the court stated:

[T]o provide effective incentives, claims must adequately protect inventors. To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for “preferred” materials in a process such as the one herein involved would not serve the constitutional purpose of promoting progress in the useful arts.

When analyzing the enabled scope of a claim, the teachings of the specification must not be ignored because claims are to be given their broadest reasonable interpretation that is consistent with the specification. “That claims are interpreted in light of the specification does not mean that everything in the specification must be read into the claims.” *Raytheon*

*Co. v. Roper Corp.*, 724 F.2d 951, 957, 220 USPQ 592, 597 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 835 (1984).

The record must be clear so that the public will have notice as to the patentee’s scope of protection when the patent issues. If a reasonable interpretation of the claim is broader than the description in the specification, it is necessary for the examiner to make sure the full scope of the claim is enabled. Limitations and examples in the specification do not generally limit what is covered by the claims.

The breadth of the claims was a factor considered in *Amgen v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir.), *cert. denied*, 502 U.S. 856 (1991). In the *Amgen* case, the patent claims were directed to a purified DNA sequence encoding polypeptides which are analogs of erythropoietin (EPO). The Court stated that:

Amgen has not enabled preparation of DNA sequences sufficient to support its all-encompassing claims. . . . [D]espite extensive statements in the specification concerning all the analogs of the EPO gene that can be made, there is little enabling disclosure of particular analogs and how to make them. Details for preparing only a few EPO analog genes are disclosed. . . . This disclosure might well justify a generic claim encompassing these and similar analogs, but it represents inadequate support for Amgen’s desire to claim all EPO gene analogs. There may be many other genetic sequences that code for EPO-type products. Amgen has told how to make and use only a few of them and is therefore not entitled to claim all of them.

927 F.2d at 1213-14, 18 USPQ2d at 1027. However, when claims are directed to any purified and isolated DNA sequence encoding a specifically named protein where the protein has a specifically identified sequence, a rejection of the claims as broader than the enabling disclosure is generally not appropriate because one skilled in the art could readily determine any one of the claimed embodiments.

See also *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) (The evidence did not show that a skilled artisan would have been able to carry out the steps required to practice the full scope of claims which encompass “any and all live, non-pathogenic vaccines, and processes for making such vaccines, which elicit immunoprotective activity in any animal toward any RNA virus.” (original emphasis)); *In re Goodman*, 11 F.3d 1046,



1052, 29 USPQ2d 2010, 2015 (Fed. Cir. 1993) (The specification did not enable the broad scope of the claims for producing mammalian peptides in plant cells because the specification contained only an example of producing gamma-interferon in a dicot species, and there was evidence that extensive experimentation would have been required for encoding mammalian peptide into a monocot plant at the time of filing); *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (Where applicant claimed a composition suitable for the treatment of arthritis having a potency of “at least” a particular value, the court held that the claim was not commensurate in scope with the enabling disclosure because the disclosure was not enabling for compositions having a slightly higher potency. Simply because applicant was the first to achieve a composition beyond a particular threshold potency did not justify or support a claim that would dominate every composition that exceeded that threshold value.); *In re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991) (Given the relatively incomplete understanding in the biotechnological field involved, and the lack of a reasonable correlation between the narrow disclosure in the specification and the broad scope of protection sought in the claims, a rejection under 35 U.S.C. 112, first paragraph for lack of enablement was appropriate.).

If a rejection is made based on the view that the enablement is not commensurate in scope with the claim, the examiner should identify the subject matter that is considered to be enabled.

### 2164.08(a) Single Means Claim

A single means claim, i.e., where a means recitation does not appear in combination with another recited element of means, is subject to an undue breadth rejection under 35 U.S.C. 112, first paragraph. *In re Hyatt*, 708 F.2d 712, 714-715, 218 USPQ 195, 197 (Fed. Cir. 1983) (A single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claim because the specification disclosed at most only those means known to the inventor.). When claims depend on a recited property, a fact situation comparable to *Hyatt* is possible, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only those known to the inventor.

### 2164.08(b) Inoperative Subject Matter

The presence of inoperative embodiments within the scope of a claim does not necessarily render a claim nonenabled. The standard is whether a skilled person could determine which embodiments that were conceived, but not yet made, would be inoperative or operative with expenditure of no more effort than is normally required in the art. *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1577, 224 USPQ 409, 414 (Fed. Cir. 1984) (prophetic examples do not make the disclosure nonenabling).

Although, typically, inoperative embodiments are excluded by language in a claim (e.g., preamble), the scope of the claim may still not be enabled where undue experimentation is involved in determining those embodiments that are operable. A disclosure of a large number of operable embodiments and the identification of a single inoperative embodiment did not render a claim broader than the enabled scope because undue experimentation was not involved in determining those embodiments that were operable. *In re Angstadt*, 537 F.2d 498, 502-503, 190 USPQ 214, 218 (CCPA 1976). However, claims reading on significant numbers of inoperative embodiments would render claims nonenabled when the specification does not clearly identify the operative embodiments and undue experimentation is involved in determining those that are operative. *Atlas Powder Co. v. E.I. duPont de Nemours & Co.*, 750 F.2d 1569, 1577, 224 USPQ 409, 414 (Fed. Cir. 1984); *In re Cook*, 439 F.2d 730, 735, 169 USPQ 298, 302 (CCPA 1971).

### 2164.08(c) Critical Feature Not Claimed

A feature which is taught as critical in a specification and is not recited in the claims should result in a rejection of such claim under the enablement provision section of 35 U.S.C. 112. See *In re Mayhew*, 527 F.2d 1229, 1233, 188 USPQ 356, 358 (CCPA 1976). In determining whether an unclaimed feature is critical, the entire disclosure must be considered. Features which are merely preferred are not to be considered critical. *In re Goffe*, 542 F.2d 564, 567, 191 USPQ 429, 431 (CCPA 1976).

Limiting an applicant to the preferred materials in the absence of limiting prior art would not serve the constitutional purpose of promoting the progress in

the useful arts. Therefore, an enablement rejection based on the grounds that a disclosed critical limitation is missing from a claim should be made only when the language of the specification makes it clear that the limitation is critical for the invention to function as intended. Broad language in the disclosure, including the abstract, omitting an allegedly critical feature, tends to rebut the argument of criticality.

## 2165 The Best Mode Requirement

A third requirement of the first paragraph of 35 U.S.C. 112 is that:

The specification . . . shall set forth the best mode contemplated by the inventor of carrying out his invention.

“The best mode requirement creates a statutory bargained-for-exchange by which a patentee obtains the right to exclude others from practicing the claimed invention for a certain time period, and the public receives knowledge of the preferred embodiments for practicing the claimed invention.” *Eli Lilly & Co. v. Barr Laboratories Inc.*, 251 F.3d 955, 963, 58 USPQ2d 1865, 1874 (Fed. Cir. 2001).

The best mode requirement is a safeguard against the desire on the part of some people to obtain patent protection without making a full disclosure as required by the statute. The requirement does not permit inventors to disclose only what they know to be their second-best embodiment, while retaining the best for themselves. *In re Nelson*, 280 F.2d 172, 126 USPQ 242 (CCPA 1960).

Determining compliance with the best mode requirement requires a two-prong inquiry. First, it must be determined whether, at the time the application was filed, the inventor possessed a best mode for practicing the invention. This is a subjective inquiry which focuses on the inventor’s state of mind at the time of filing. Second, if the inventor did possess a best mode, it must be determined whether the written description disclosed the best mode such that a person skilled in the art could practice it. This is an objective inquiry, focusing on the scope of the claimed invention and the level of skill in the art. *Eli Lilly & Co. v. Barr Laboratories Inc.*, 251 F.3d 955, 963, 58 USPQ2d 1865, 1874 (Fed. Cir. 2001).

The failure to disclose a better method will not invalidate a patent if the inventor, at the time of filing the application, did not know of the better method OR

did not appreciate that it was the best method. All applicants are required to disclose for the claimed subject matter the best mode contemplated by the inventor even though applicant may not have been the discoverer of that mode. *Benger Labs. Ltd. v. R.K. Laros Co.*, 209 F. Supp. 639, 135 USPQ 11 (E.D. Pa. 1962).

## ACTIVE CONCEALMENT OR GROSSLY INEQUITABLE CONDUCT IS NOT REQUIRED TO ESTABLISH FAILURE TO DISCLOSE THE BEST MODE

Failure to disclose the best mode need not rise to the level of active concealment or grossly inequitable conduct in order to support a rejection or invalidate a patent. Where an inventor knows of a specific material that will make possible the successful reproduction of the effects claimed by the patent, but does not disclose it, speaking instead in terms of broad categories, the best mode requirement has not been satisfied. *Union Carbide Corp. v. Borg-Warner*, 550 F.2d 555, 193 USPQ 1 (6th Cir. 1977).

If the failure to set forth the best mode in a patent disclosure is the result of inequitable conduct (e.g., where the patent specification omitted crucial ingredients and disclosed a fictitious and inoperable slurry as Example 1), not only is that patent in danger of being held unenforceable, but other patents dealing with the same technology that are sought to be enforced in the same cause of action are subject to being held unenforceable. *Consolidated Aluminum Corp. v. Foseco Inc.*, 910 F.2d 804, 15 USPQ2d 1481 (Fed. Cir. 1990).

## 2165.01 Considerations Relevant to Best Mode [R-2]

### I. DETERMINE WHAT IS THE INVENTION

Determine what the invention is — the invention is defined in the claims. The specification need not set forth details not relating to the essence of the invention. *In re Bosy*, 360 F.2d 972, 149 USPQ 789 (CCPA 1966). See also *Northern Telecom Ltd. v. Samsung Electronics Co.*, 215 F.3d 1281, 55 USPQ2d 1065 (Fed. Cir. 2000) (Unclaimed matter that is unrelated to the operation of the claimed invention does not trigger the best mode requirement); *Eli Lilly & Co. v. Barr Laboratories Inc.*, 251 F.3d 955, 966, 58 USPQ2d 1865, 1877 (Fed. Cir. 2001) (“[P]atentee’s

failure to disclose an unclaimed preferred mode for accomplishing a routine detail does not violate the best mode requirement because one skilled in the art is aware of alternative means for accomplishing the routine detail that would still produce the best mode of the claimed invention.”).

## II. SPECIFIC EXAMPLE IS NOT REQUIRED

There is no statutory requirement for the disclosure of a specific example — a patent specification is not intended nor required to be a production specification. *In re Gay*, 309 F.2d 768, 135 USPQ 311 (CCPA 1962).

The absence of a specific working example is not necessarily evidence that the best mode has not been disclosed, nor is the presence of one evidence that it has. Best mode may be represented by a preferred range of conditions or group of reactants. *In re Honn*, 364 F.2d 454, 150 USPQ 652 (CCPA 1966).

## III. DESIGNATION AS BEST MODE IS NOT REQUIRED

There is no requirement in the statute that applicants point out which of their embodiments they consider to be their best; that the disclosure includes the best mode contemplated by applicants is enough to satisfy the statute. *Ernsthausen v. Nakayama*, 1 USPQ2d 1539 (Bd. Pat. App. & Inter. 1985).

## IV. UPDATING BEST MODE IS NOT REQUIRED

There is no requirement to update in the context of a foreign priority application under 35 U.S.C. 119, *Standard Oil Co. v. Montedison, S.p.A.*, 494 F.Supp. 370, 206 USPQ 676 (D.Del. 1980) (better catalyst developed between Italian priority and U.S. filing dates), and continuing applications claiming the benefit of an earlier filing date under 35 U.S.C. 120, *Transco Products, Inc. v. Performance Contracting Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994) (continuation under >former< 37 CFR 1.60); *Sylgab Steel and Wire Corp. v. Imoco-Gateway Corp.*, 357 F.Supp. 657, 178 USPQ 22 (N.D. Ill. 1973) (continuation); *Johns-Manville Corp. v. Guardian Industries Corp.*, 586 F.Supp. 1034, 221 USPQ 319 (E.D. Mich. 1983) (continuation and CIP). In the last cited case, the court stated that applicant would have been obliged to disclose an updated refinement if it were

essential to the successful practice of the invention and it related to amendments to the CIP that were not present in the parent application. In *Carter-Wallace, Inc. v. Riverton Labs., Inc.*, 433 F.2d 1034, 167 USPQ 656 (2d Cir. 1970), the court assumed, but did not decide, that an applicant must update the best mode when filing a CIP application.

## V. DEFECT IN BEST MODE CANNOT BE CURED BY NEW MATTER

If the best mode contemplated by the inventor at the time of filing the application is not disclosed, such a defect cannot be cured by submitting an amendment seeking to put into the specification something required to be there when the patent application was originally filed. *In re Hay*, 534 F.2d 917, 189 USPQ 790 (CCPA 1976).

Any proposed amendment of this type (adding a specific mode of practicing the invention not described in the application as filed) should be treated as new matter. New matter under 35 U.S.C. 132 and 251 should be objected to and coupled with a requirement to cancel the new matter.

## 2165.02 Best Mode Requirement Compared to Enablement Requirement

The best mode requirement is a separate and distinct requirement from the enablement requirement of the first paragraph of 35 U.S.C. 112. *In re Newton*, 414 F.2d 1400, 163 USPQ 34 (CCPA 1969).

The best mode provision of 35 U.S.C. 112 is not directed to a situation where the application fails to set forth any mode — such failure is equivalent to nonenablement. *In re Glass*, 492 F.2d 1228, 181 USPQ 31 (CCPA 1974).

The enablement requirement looks to placing the subject matter of the claims generally in the possession of the public. If, however, the applicant develops specific instrumentalities or techniques which are recognized by the applicant at the time of filing as the best way of carrying out the invention, then the best mode requirement imposes an obligation to disclose that information to the public as well. *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 3 USPQ 2d 1737 (Fed. Cir.), *cert. denied*, 484 U.S. 954 (1987).

### 2165.03 Requirements for Rejection for Lack of Best Mode [R-1]

#### ASSUME BEST MODE IS DISCLOSED UNLESS THERE IS EVIDENCE TO THE CONTRARY

The examiner should assume that the best mode is disclosed in the application, unless evidence is presented that is inconsistent with that assumption. It is extremely rare that a best mode rejection properly would be made in *ex parte* prosecution. The information that is necessary to form the basis for a rejection based on the failure to set forth the best mode is rarely accessible to the examiner, but is generally uncovered during discovery procedures in interference, litigation, or other *inter partes* proceedings.

#### EXAMINER MUST DETERMINE WHETHER THE INVENTOR KNEW THAT ONE MODE WAS BETTER THAN ANOTHER, AND IF SO, WHETHER THE DISCLOSURE IS ADEQUATE TO ENABLE ONE OF ORDINARY SKILL IN THE ART TO PRACTICE THE BEST MODE

According to the approach used by the court in *Chemcast Corp. v. Arco Industries*, 913 F.2d 923, 16 USPQ2d 1033 (Fed. Cir. 1990), a proper best mode analysis has two components:

(A) >Determine whether, at the time the application was filed, the inventor knew of a mode of practicing the claimed invention that the inventor considered to be better than any other.<

The first component is a subjective inquiry because it focuses on the inventor's state of mind at the time the application was filed. Unless the examiner has evidence that the inventors had information in their possession

(1) at the time the application was filed

(2) that a mode was considered to be better than any others by the inventors,

there is no reason to address the second component and there is no proper basis for a best mode rejection. If the facts satisfy the first component, then, and only then, is the following second component analyzed:

(B) Compare what was known in (A) with what was disclosed - is the disclosure adequate to enable one skilled in the art to practice the best mode?

Assessing the adequacy of the disclosure in this regard is largely an objective inquiry that depends on the level of skill in the art. Is the information contained in the specification disclosure sufficient to enable a person skilled in the relevant art to make and use the best mode?

A best mode rejection is proper only when the first inquiry can be answered in the affirmative, and the second inquiry answered in the negative with reasons to support the conclusion that the specification is non-enabling with respect to the best mode.

### 2165.04 Examples of Evidence of Concealment

In determining the adequacy of a best mode disclosure, only evidence of concealment (accidental or intentional) is to be considered. That evidence must tend to show that the quality of an applicant's best mode disclosure is so poor as to effectively result in concealment.

#### I. EXAMPLES — BEST MODE REQUIREMENT SATISFIED

In one case, even though the inventor had more information in his possession concerning the contemplated best mode than was disclosed (a known computer program) the specification was held to delineate the best mode in a manner sufficient to require only the application of routine skill to produce a workable digital computer program. *In re Sherwood*, 613 F.2d 809, 204 USPQ 537 (CCPA 1980).

In another case, the claimed subject matter was a time controlled thermostat, but the application did not disclose the specific Quartzmatic motor which was used in a commercial embodiment. The Court concluded that failure to disclose the commercial motor did not amount to concealment since similar clock motors were widely available and widely advertised. There was no evidence that the specific Quartzmatic motor was superior except possibly in price. *Honeywell v. Diamond*, 208 USPQ 452 (D.D.C. 1980).

There was held to be no violation of the best mode requirement even though the inventor did not disclose the only mode of calculating the stretch rate for plastic rods that he used because that mode would have been employed by those of ordinary skill in the art at the time the application was filed. *W.L. Gore &*

*Assoc., Inc. v. Garlock Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983).

There was no best mode violation where there was no evidence that the monoclonal antibodies used by the inventors differed from those obtainable according to the processes described in the specification. It was not disputed that the inventors obtained the antibodies used in the invention by following the procedures in the specification, that these were the inventors' preferred procedures, and that the data reported in the specification was for the antibody that the inventors had actually used. *Scripps Clinic and Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 18 USPQ 2d 1001 (Fed. Cir. 1991).

Where an organism was created by the insertion of genetic material into a cell obtained from generally available sources, all that was required to satisfy the best mode requirement was an adequate description of the means for carrying out the invention, not deposit of the cells. As to the observation that no scientist could ever duplicate exactly the cell used by applicants, the court observed that the issue is whether the disclosure is adequate, not that an exact duplication is necessary. *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ 2d 1016 (Fed. Cir. 1991).

There was held to be no violation of the best mode requirement where the Solicitor argued that concealment could be inferred from the disclosure in a specification that each analog is "surprisingly and unexpectedly more useful than one of the corresponding prostaglandins . . . for at least one of the pharmacological purposes." It was argued that appellant must have had test results to substantiate this statement and this data should have been disclosed. The court concluded that no withholding could be inferred from general statements of increased selectivity and narrower spectrum of potency for these novel analogs, conclusions which could be drawn from the elementary pharmacological testing of the analogs. *In re Bundy*, 642 F.2d 430, 435, 209 USPQ 48, 52 (CCPA 1981).

## II. EXAMPLES — BEST MODE REQUIREMENT NOT SATISFIED

The best mode requirement was held to be violated where inventors of a laser failed to disclose details of their preferred TiCuSil brazing method which were not contained in the prior art and were contrary to cri-

teria for the use of TiCuSil as contained in the literature. *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 3 USPQ 2d 1737 (Fed. Cir. 1987).

The best mode requirement was violated because an inventor failed to disclose whether to use a specific surface treatment that he knew was necessary to the satisfactory performance of his invention, even though how to perform the treatment itself was known in the art. The argument that the best mode requirement may be met solely by reference to what was known in the prior art was rejected as incorrect. *Dana Corp. v. IPC Ltd. Partnership*, 860 F.2d 415, 8 USPQ2d 1692 (Fed. Cir. 1988).

## 2171 Two Separate Requirements for Claims Under 35 U.S.C. 112, Second Paragraph

The second paragraph of 35 U.S.C. 112 is directed to requirements for the claims:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

There are two separate requirements set forth in this paragraph:

(A) the claims must set forth the subject matter that applicants regard as their invention; and

(B) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant.

The first requirement is a subjective one because it is dependent on what the applicants for a patent regard as their invention. The second requirement is an objective one because it is not dependent on the views of applicant or any particular individual, but is evaluated in the context of whether the claim is definite — i.e., whether the scope of the claim is clear to a hypothetical person possessing the ordinary level of skill in the pertinent art.

Although an essential purpose of the examination process is to determine whether or not the claims define an invention that is both novel and nonobvious over the prior art, another essential purpose of patent examination is to determine whether or not the claims are precise, clear, correct, and unambiguous. The uncertainties of claim scope should be removed, as much as possible, during the examination process.

The inquiry during examination is patentability of the invention as applicant regards it. If the claims do not particularly point out and distinctly claim that which applicants regard as their invention, the appropriate action by the examiner is to reject the claims under 35 U.S.C. 112, second paragraph. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). If a rejection is based on 35 U.S.C. 112, second paragraph, the examiner should further explain whether the rejection is based on indefiniteness or on the failure to claim what applicants regard as their invention. *Ex parte Ionescu*, 222 USPQ 537, 539 (Bd. App. 1984).

## 2172 Subject Matter Which Applicants Regard as Their Invention

### I. FOCUS FOR EXAMINATION

A rejection based on the failure to satisfy this requirement is appropriate only where applicant has stated, somewhere other than in the application as filed, that the invention is something different from what is defined by the claims. In other words, the invention set forth in the claims must be presumed, in the absence of evidence to the contrary, to be that which applicants regard as their invention. *In re Moore*, 439 F.2d 1232, 169 USPQ 236 (CCPA 1971).

### II. EVIDENCE TO THE CONTRARY

Evidence that shows that a claim does not correspond in scope with that which applicant regards as applicant's invention may be found, for example, in contentions or admissions contained in briefs or remarks filed by applicant, *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 55 USPQ2d 1279 (Fed. Cir. 2000); *In re Prater*, 415 F.2d 1393, 162 USPQ 541 (CCPA 1969), or in affidavits filed under 37 CFR 1.132, *In re Cormany*, 476 F.2d 998, 177 USPQ 450 (CCPA 1973). The content of applicant's specification is not used as evidence that the scope of the claims is inconsistent with the subject matter which applicants regard as their invention. As noted in *In re Ehrreich*, 590 F.2d 902, 200 USPQ 504 (CCPA 1979), agreement, or lack thereof, between the claims and the specification is properly considered only with respect to 35 U.S.C. 112, first paragraph; it is irrelevant to compliance with the second paragraph of that section.

### III. SHIFT IN CLAIMS PERMITTED

The second paragraph of 35 U.S.C. 112 does not prohibit applicants from changing what they regard as their invention during the pendency of the application. *In re Saunders*, 444 F.2d 599, 170 USPQ 213 (CCPA 1971) (Applicant was permitted to claim and submit comparative evidence with respect to claimed subject matter which originally was only the preferred embodiment within much broader claims (directed to a method)). The fact that claims in a continuation application were directed to originally disclosed subject matter which applicants had not regarded as part of their invention when the parent application was filed was held not to prevent the continuation application from receiving benefits of the filing date of the parent application under 35 U.S.C. 120. *In re Brower*, 433 F.2d 813, 167 USPQ 684 (CCPA 1970).

#### 2172.01 Unclaimed Essential Matter [R-1]

A claim which omits matter disclosed to be essential to the invention as described in the specification or in other statements of record may be rejected under 35 U.S.C. 112, first paragraph, as not enabling. *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). See also MPEP § 2164.08(c). Such essential matter may include missing elements, steps or necessary structural cooperative relationships of elements described by the applicant(s) as necessary to practice the invention.

In addition, a claim which fails to interrelate essential elements of the invention as defined by applicant(s) in the specification may be rejected under 35 U.S.C. 112, second paragraph, for failure to point out and distinctly claim the invention. See *In re Venezia*, 530 F.2d 956, 189 USPQ 149 (CCPA 1976); *In re Collier*, 397 F.2d 1003, 158 USPQ 266 (CCPA 1968). >But see *Ex parte Nolden*, 149 USPQ 378, 380 (Bd. Pat. App. 1965) ("[I]t is not essential to a patentable combination that there be interdependency between the elements of the claimed device or that all the elements operate concurrently toward the desired result"); *Ex parte Huber*, 148 USPQ 447, 448-49 (Bd. Pat. App. 1965) (A claim does not necessarily fail to comply with 35 U.S.C. 112, second paragraph where the various elements do not function simultaneously,

are not directly functionally related, do not directly intercooperate, and/or serve independent purposes.)<

## 2173 Claims Must Particularly Point Out and Distinctly Claim the Invention

The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability and whether the specification meets the criteria of 35 U.S.C. 112, first paragraph with respect to the claimed invention.

### 2173.01 Claim Terminology [R-2]

A fundamental principle contained in 35 U.S.C. 112, second paragraph is that applicants are their own lexicographers. They can define in the claims what they regard as their invention essentially in whatever terms they choose so long as \*\*>any special meaning assigned to a term is clearly set forth in the specification. See MPEP § 2111.01.< Applicant may use functional language, alternative expressions, negative limitations, or any style of expression or format of claim which makes clear the boundaries of the subject matter for which protection is sought. As noted by the court in *In re Swinehart*, 439 F.2d 210, 160 USPQ 226 (CCPA 1971), a claim may not be rejected solely because of the type of language used to define the subject matter for which patent protection is sought.

### 2173.02 Clarity and Precision [R-1]

The examiner's focus during examination of claims for compliance with the requirement for definiteness of 35 U.S.C. 112, second paragraph, is whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available. When the examiner is satisfied that patentable subject matter is disclosed, and it is apparent to the examiner that the claims are directed to such patentable subject matter, he or she should allow claims which define the patentable subject matter with a reasonable degree of particularity and distinctness. Some latitude in the manner

of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire. Examiners are encouraged to suggest claim language to applicants to improve the clarity or precision of the language used, but should not reject claims or insist on their own preferences if other modes of expression selected by applicants satisfy the statutory requirement.

The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of:

- (A) The content of the particular application disclosure;
- (B) The teachings of the prior art; and
- (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

In reviewing a claim for compliance with 35 U.S.C. 112, second paragraph, the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. 112, second paragraph, >by providing clear warning to others as to what constitutes infringement of the patent<. See, e.g., *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1379, 55 USPQ2d 1279, 1283 (Fed. Cir. 2000). See also *In re Larsen*, No. 01-1092 (Fed. Cir. May 9, 2001) (unpublished) (The preamble of the *Larsen* claim recited only a hanger and a loop but the body of the claim positively recited a linear member. The court observed that the totality of all the limitations of the claim and their interaction with each other must be considered to ascertain the inventor's contribution to the art. Upon review of the claim in its entirety, the court concluded that the claim at issue apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. 112 paragraph 2.).

>If the language of the claim is such that a person of ordinary skill in the art could not interpret the metes and bounds of the claim so as to understand how to avoid infringement, a rejection of the claim under 35 U.S.C. 112, second paragraph, would be appropriate. See *Morton Int'l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470, 28 USPQ2d 1190, 1195 (Fed.



Cir. 1993). However, if the language used by applicant satisfies the statutory requirements of 35 U.S.C. 112, second paragraph, but the examiner merely wants the applicant to improve the clarity or precision of the language used, the claim must not be rejected under 35 U.S.C. 112, second paragraph, rather, the examiner should suggest improved language to the applicant.

For example, a claim recites “a suitable liquid such as the filtrate of the contaminated liquid to be filtered and solids of a filtering agent such as perlite, cellulose powder, etc.” The mere use of the phrase “such as” in the claim does not by itself render the claim indefinite. Office policy is not to employ *per se* rules to make technical rejections. Examples of claim language which have been held to be indefinite set forth in MPEP § 2173.05(d) are fact specific and should not be applied as *per se* rules. The test for definiteness under 35 U.S.C. 112, second paragraph, is whether “those skilled in the art would understand what is claimed when the claim is read in light of the specification.” *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986). If one skilled in the art is able to ascertain in the example above, the meaning of the terms “suitable liquid” and “solids of a filtering agent” in light of the specification, 35 U.S.C. 112, second paragraph, is satisfied. If upon review of the claim as a whole in light of the specification, the examiner determines that a rejection under 35 U.S.C. 112, second paragraph, is not appropriate in the above-noted example, but is of the opinion that the clarity and the precision of the language can be improved by the deletion of the phrase “such as” in the claim, the examiner may make such a suggestion to the applicant. If applicant does not accept the examiner’s suggestion, the examiner should not pursue the issue.

If upon review of a claim in its entirety, the examiner concludes that a rejection under 35 U.S.C. 112, second paragraph, is appropriate, such a rejection should be made and an analysis as to why the phrase(s) used in the claim is “vague and indefinite” should be included in the Office action. If applicants traverse the rejection, with or without the submission of an amendment, and the examiner considers applicant’s arguments to be persuasive, the examiner should indicate in the next Office communication that

the previous rejection under 35 U.S.C. 112, second paragraph, has been withdrawn and provide an explanation as to what prompted the change in the examiner’s position (e.g., examiners may make specific reference to portions of applicant’s remarks that were considered to be the basis as to why the previous rejection was withdrawn).

By providing an explanation as to the action taken, the examiner will enhance the clarity of the prosecution history record. As noted by the Supreme Court in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 122 S.Ct. 1831, 1838, 62 USPQ2d 1705, 1710 (2002), a clear and complete prosecution file record is important in that “[p]rosecution history estoppel requires that the claims of a patent be interpreted in light of the proceedings in the PTO during the application process.” In *Festo*, the court held that “a narrowing amendment made to satisfy any requirement of the Patent Act may give rise to an estoppel.” With respect to amendments made to comply with the requirements of 35 U.S.C. 112, the court stated that “[i]f a § 112 amendment is truly cosmetic, then it would not narrow the patent’s scope or raise an estoppel. On the other hand, if a § 112 amendment is necessary and narrows the patent’s scope—even if only for the purpose of better description—estoppel may apply.” *Id.*, at 1840, 62 USPQ2d at 1712. The court further stated that “when the court is unable to determine the purpose underlying a narrowing amendment—and hence a rationale for limiting the estoppel to the surrender of particular equivalents—the court should presume that the patentee surrendered all subject matter between the broader and the narrower language...the patentee should bear the burden of showing that the amendment does not surrender the particular equivalent in question.” *Id.*, at 1842, 62 USPQ2d at 1713. Thus, whenever possible, the examiner should make the record clear by providing explicit reasoning for making or withdrawing any rejection related to 35 U.S.C. 112, second paragraph.<

### **2173.03 Inconsistency Between Claim \*>and< Specification Disclosure or Prior Art [R-1]**

Although the terms of a claim may appear to be definite, inconsistency with the specification disclosure or prior art teachings may make an otherwise definite claim take on an unreasonable degree of



uncertainty. *In re Cohn*, 438 F.2d 989, 169 USPQ 95 (CCPA 1971); *In re Hammack*, 427 F.2d 1378, 166 USPQ 204 (CCPA 1970). In *Cohn*, the claim was directed to a process of treating a surface with a corroding solution until the metallic appearance is supplanted by an “opaque” appearance. Noting that no claim may be read apart from and independent of the supporting disclosure on which it is based, the court found that the description, definitions and examples set forth in the specification relating to the appearance of the surface after treatment were inherently inconsistent and rendered the claim indefinite.

#### 2173.04 Breadth Is Not Indefiniteness

Breadth of a claim is not to be equated with indefiniteness. *In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971). If the scope of the subject matter embraced by the claims is clear, and if applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. 112, second paragraph.

Undue breadth of the claim may be addressed under different statutory provisions, depending on the reasons for concluding that the claim is too broad. If the claim is too broad because it does not set forth that which applicants regard as their invention as evidenced by statements outside of the application as filed, a rejection under 35 U.S.C. 112, second paragraph, would be appropriate. If the claim is too broad because it is not supported by the original description or by an enabling disclosure, a rejection under 35 U.S.C. 112, first paragraph, would be appropriate. If the claim is too broad because it reads on the prior art, a rejection under either 35 U.S.C. 102 or 103 would be appropriate.

#### 2173.05 Specific Topics Related to Issues Under 35 U.S.C. 112, Second Paragraph [R-1]

The following sections are devoted to a discussion of specific topics where issues under 35 U.S.C. 112, second paragraph, have been addressed. These sections are not intended to be an exhaustive list of the issues that can arise under 35 U.S.C. 112, second paragraph, but are intended to provide guidance in areas that have been addressed with some frequency

in recent examination practice. The court and Board decisions cited are representative. As with all appellate decisions, the results are largely dictated by the facts in each case. The use of the same language in a different context may justify a different result.

>See MPEP § 2181 for guidance in determining whether an applicant has complied with the requirements of 35 U.S.C. 112, second paragraph, when 35 U.S.C. 112, sixth paragraph, is invoked.<

#### 2173.05(a) New Terminology [R-2]

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##### I. <THE MEANING OF EVERY TERM SHOULD BE APPARENT

The meaning of every term used in a claim should be apparent from the prior art or from the specification and drawings at the time the application is filed. Applicants need not confine themselves to the terminology used in the prior art, but are required to make clear and precise the terms that are used to define the invention whereby the metes and bounds of the claimed invention can be ascertained. During patent examination, the pending claims must be given the broadest reasonable interpretation consistent with the specification. *In re Morris*, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997); *In re Prater*, 415 F.2d 1393, 162 USPQ 541 (CCPA 1969). See also MPEP § 2111 - § 2111.01. When the specification states the meaning that a term in the claim is intended to have, the claim is examined using that meaning, in order to achieve a complete exploration of the applicant's invention and its relation to the prior art. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989).

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##### II. <THE REQUIREMENT FOR CLARITY AND PRECISION MUST BE BALANCED WITH THE LIMITATIONS OF THE LANGUAGE

Courts have recognized that it is not only permissible, but often desirable, to use new terms that are frequently more precise in describing and defining the new invention. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970). Although it is difficult to compare the claimed invention with the prior art when new

terms are used that do not appear in the prior art, this does not make the new terms indefinite.

New terms are often used when a new technology is in its infancy or is rapidly evolving. The requirements for clarity and precision must be balanced with the limitations of the language and the science. If the claims, read in light of the specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the statute (35 U.S.C. 112, second paragraph) demands no more. *Shatterproof Glass Corp. v. Libbey Owens Ford Co.*, 758 F.2d 613, 225 USPQ 634 (Fed. Cir. 1985) (interpretation of “freely supporting” in method claims directed to treatment of a glass sheet); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (Fed. Cir. 1986) (interpretation of a limitation specifying a numerical value for antibody affinity where the method of calculation was known in the art at the time of filing to be imprecise). This does not mean that the examiner must accept the best effort of applicant. If the proposed language is not considered as precise as the subject matter permits, the examiner should provide reasons to support the conclusion of indefiniteness and is encouraged to suggest alternatives that are free from objection.

>

### III. <TERMS USED CONTRARY TO THEIR ORDINARY MEANING MUST BE CLEARLY REDEFINED IN THE WRITTEN DESCRIPTION

Consistent with the well-established axiom in patent law that a patentee or applicant is free to be his or her own lexicographer, a patentee or applicant may use terms in a manner contrary to or inconsistent with one or more of their ordinary meanings if the written description clearly redefines the terms. See, e.g., *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999) (“While we have held many times that a patentee can act as his own lexicographer to specifically define terms of a claim contrary to their ordinary meaning,” in such a situation the written description must clearly redefine a claim term “so as to put a reasonable competitor or one reasonably skilled in the art on notice that the patentee intended to so redefine that claim term.”); *Hormone Research Foundation Inc. v.*

*Genentech Inc.*, 904 F.2d 1558, 15 USPQ2d 1039 (Fed. Cir. 1990). Accordingly, when there is more than one definition for a term, it is incumbent upon applicant to make clear which definition is being relied upon to claim the invention. Until the meaning of a term or phrase used in a claim is clear, a rejection under 35 U.S.C. 112, second paragraph is appropriate. >In applying the prior art, the claims should be construed to encompass all definitions that are consistent with applicant’s use of the term. See *Tex. Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1202, 64 USPQ2d 1812, 1818 (Fed. Cir. 2002).< It is appropriate to compare the meaning of terms given in technical dictionaries in order to ascertain the accepted meaning of a term in the art. *In re Barr*, 444 F.2d 588, 170 USPQ 330 (CCPA 1971).

### 2173.05(b) Relative Terminology

The fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. 112, second paragraph. *Seattle Box Co., v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984). Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification.

### WHEN A TERM OF DEGREE IS PRESENT, DETERMINE WHETHER A STANDARD IS DISCLOSED OR WHETHER ONE OF ORDINARY SKILL IN THE ART WOULD BE APPRISED OF THE SCOPE OF THE CLAIM

When a term of degree is presented in a claim, first a determination is to be made as to whether the specification provides some standard for measuring that degree. If it does not, a determination is made as to whether one of ordinary skill in the art, in view of the prior art and the status of the art, would be nevertheless reasonably apprised of the scope of the invention. Even if the specification uses the same term of degree as in the claim, a rejection may be proper if the scope of the term is not understood when read in light of the specification. While, as a general proposition, broadening modifiers are standard tools in claim drafting in order to avoid reliance on the doctrine of equivalents in infringement actions, when the scope of the claim is unclear a rejection under 35 U.S.C. 112, second

paragraph, is proper. See *In re Wiggins*, 488 F. 2d 538, 541, 179 USPQ 421, 423 (CCPA 1973).

When relative terms are used in claims wherein the improvement over the prior art rests entirely upon size or weight of an element in a combination of elements, the adequacy of the disclosure of a standard is of greater criticality.

#### REFERENCE TO AN OBJECT THAT IS VARIABLE MAY RENDER A CLAIM INDEFINITE

A claim may be rendered indefinite by reference to an object that is variable. For example, the Board has held that a limitation in a claim to a bicycle that recited "said front and rear wheels so spaced as to give a wheelbase that is between 58 percent and 75 percent of the height of the rider that the bicycle was designed for" was indefinite because the relationship of parts was not based on any known standard for sizing a bicycle to a rider, but on a rider of unspecified build. *Ex parte Brummer*, 12 USPQ2d 1653 (Bd. Pat. App. & Inter. 1989). On the other hand, a claim limitation specifying that a certain part of a pediatric wheelchair be "so dimensioned as to be insertable through the space between the doorframe of an automobile and one of the seats" was held to be definite. *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1 USPQ2d 1081 (Fed. Cir. 1986). The court stated that the phrase "so dimensioned" is as accurate as the subject matter permits, noting that the patent law does not require that all possible lengths corresponding to the spaces in hundreds of different automobiles be listed in the patent, let alone that they be listed in the claims.

##### A. "About"

The term "about" used to define the area of the lower end of a mold as between 25 to about 45% of the mold entrance was held to be clear, but flexible. *Ex parte Eastwood*, 163 USPQ 316 (Bd. App. 1968). Similarly, in *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), the court held that a limitation defining the stretch rate of a plastic as "exceeding about 10% per second" is definite because infringement could clearly be assessed through the use of a stopwatch. However, the court held that claims reciting "at least about" were invalid for indefiniteness where there was close prior art and there was nothing in the specification, prose-

cution history, or the prior art to provide any indication as to what range of specific activity is covered by the term "about." *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991).

##### B. "Essentially"

The phrase "a silicon dioxide source that is essentially free of alkali metal" was held to be definite because the specification contained guidelines and examples that were considered sufficient to enable a person of ordinary skill in the art to draw a line between unavoidable impurities in starting materials and essential ingredients. *In re Marosi*, 710 F.2d 799, 218 USPQ 289 (CCPA 1983). The court further observed that it would be impractical to require applicants to specify a particular number as a cutoff between their invention and the prior art.

##### C. "Similar"

The term "similar" in the preamble of a claim that was directed to a nozzle "for high-pressure cleaning units or similar apparatus" was held to be indefinite since it was not clear what applicant intended to cover by the recitation "similar" apparatus. *Ex parte Kristensen*, 10 USPQ2d 1701 (Bd. Pat. App. & Inter. 1989).

A claim in a design patent application which read: "The ornamental design for a feed bunk or similar structure as shown and described." was held to be indefinite because it was unclear from the specification what applicant intended to cover by the recitation of "similar structure." *Ex parte Pappas*, 23 USPQ2d 1636 (Bd. Pat. App. & Inter. 1992).

##### D. "Substantially"

The term "substantially" is often used in conjunction with another term to describe a particular characteristic of the claimed invention. It is a broad term. *In re Nehrenberg*, 280 F.2d 161, 126 USPQ 383 (CCPA 1960). The court held that the limitation "to substantially increase the efficiency of the compound as a copper extractant" was definite in view of the general guidelines contained in the specification. *In re Mattison*, 509 F.2d 563, 184 USPQ 484 (CCPA 1975). The court held that the limitation "which produces substantially equal E and H plane illumination patterns" was definite because one of ordinary skill in the art

would know what was meant by “substantially equal.” *Andrew Corp. v. Gabriel Electronics*, 847 F.2d 819, 6 USPQ2d 2010 (Fed. Cir. 1988).

#### **E. “Type”**

The addition of the word “type” to an otherwise definite expression (e.g., Friedel-Crafts catalyst) extends the scope of the expression so as to render it indefinite. *Ex parte Copenhaver*, 109 USPQ 118 (Bd. App. 1955). Likewise, the phrase “ZSM-5-type aluminosilicate zeolites” was held to be indefinite because it was unclear what “type” was intended to convey. The interpretation was made more difficult by the fact that the zeolites defined in the dependent claims were not within the genus of the type of zeolites defined in the independent claim. *Ex parte Attig*, 7 USPQ2d 1092 (Bd. Pat. App. & Inter. 1986).

#### **F. Other Terms**

The phrases “relatively shallow,” “of the order of,” “the order of about 5mm,” and “substantial portion” were held to be indefinite because the specification lacked some standard for measuring the degree intended and, therefore, properly rejected as indefinite under 35 U.S.C. 112, second paragraph. *Ex parte Oetiker*, 23 USPQ2d 1641 (Bd. Pat. App. & Inter. 1992).

The term “or like material” in the context of the limitation “coke, brick, or like material” was held to render the claim indefinite since it was not clear how the materials other than coke or brick had to resemble the two specified materials to satisfy the limitations of the claim. *Ex parte Caldwell*, 1906 C.D. 58 (Comm’r Pat. 1906).

The terms “comparable” and “superior” were held to be indefinite in the context of a limitation relating the characteristics of the claimed material to other materials - “properties that are superior to those obtained with comparable” prior art materials. *Ex parte Anderson*, 21 USPQ2d 1241 (Bd. Pat. App. & Inter. 1991). It was not clear from the specification which properties had to be compared and how comparable the properties would have to be to determine infringement issues. Further, there was no guidance as to the meaning of the term “superior.”

### **2173.05(c) Numerical Ranges and Amounts Limitations**

Generally, the recitation of specific numerical ranges in a claim does not raise an issue of whether a claim is definite.

#### **I. NARROW AND BROADER RANGES IN THE SAME CLAIM**

Use of a narrow numerical range that falls within a broader range in the same claim may render the claim indefinite when the boundaries of the claim are not discernible. Description of examples and preferences is properly set forth in the specification rather than in a single claim. A narrower range or preferred embodiment may also be set forth in another independent claim or in a dependent claim. If stated in a single claim, examples and preferences lead to confusion over the intended scope of the claim. In those instances where it is not clear whether the claimed narrower range is a limitation, a rejection under 35 U.S.C. 112, second paragraph should be made. The Examiner should analyze whether the metes and bounds of the claim are clearly set forth. Examples of claim language which have been held to be indefinite are (A) “a temperature of between 45 and 78 degrees Celsius, preferably between 50 and 60 degrees Celsius”; and (B) “a predetermined quantity, for example, the maximum capacity.”

While a single claim that includes both a broad and a narrower range may be indefinite, it is not improper under 35 U.S.C. 112, second paragraph, to present a dependent claim that sets forth a narrower range for an element than the range set forth in the claim from which it depends. For example, if claim 1 reads “A circuit ... wherein the resistance is 70-150 ohms.” and claim 2 reads “The circuit of claim 1 wherein the resistance is 70-100 ohms.”, then claim 2 should not be rejected as indefinite.

#### **II. OPEN-ENDED NUMERICAL RANGES**

Open-ended numerical ranges should be carefully analyzed for definiteness. For example, when an independent claim recites a composition comprising “at least 20% sodium” and a dependent claim sets forth specific amounts of nonsodium ingredients which add up to 100%, apparently to the exclusion of sodium, an ambiguity is created with regard to the “at least”

limitation (unless the percentages of the nonsodium ingredients are based on the weight of the nonsodium ingredients). On the other hand, the court held that a composition claimed to have a theoretical content greater than 100% (i.e., 20-80% of A, 20-80% of B and 1-25% of C) was not indefinite simply because the claims may be read in theory to include compositions that are impossible in fact to formulate. It was observed that subject matter which cannot exist in fact can neither anticipate nor infringe a claim. *In re Kroekel*, 504 F.2d 1143, 183 USPQ 610 (CCPA 1974).

In a claim directed to a chemical reaction process, a limitation required that the amount of one ingredient in the reaction mixture should "be maintained at less than 7 mole percent" based on the amount of another ingredient. The examiner argued that the claim was indefinite because the limitation sets only a maximum amount and is inclusive of substantially no ingredient resulting in termination of any reaction. The court did not agree because the claim was clearly directed to a reaction process which did not warrant distorting the overall meaning of the claim to preclude performing the claimed process. *In re Kirsch*, 498 F.2d 1389, 182 USPQ 286 (CCPA 1974).

Some terms have been determined to have the following meanings in the factual situations of the reported cases: the term "up to" includes zero as a lower limit, *In re Mochel*, 470 F.2d 638, 176 USPQ 194 (CCPA 1974); and "a moisture content of not more than 70% by weight" reads on dry material, *Ex parte Khusid*, 174 USPQ 59 (Bd. App. 1971).

### III. "EFFECTIVE AMOUNT"

The common phrase "an effective amount" may or may not be indefinite. The proper test is whether or not one skilled in the art could determine specific values for the amount based on the disclosure. See *In re Mattison*, 509 F.2d 563, 184 USPQ 484 (CCPA 1975). The phrase "an effective amount . . . for growth stimulation" was held to be definite where the amount was not critical and those skilled in the art would be able to determine from the written disclosure, including the examples, what an effective amount is. *In re Halleck*, 422 F.2d 911, 164 USPQ 647 (CCPA 1970). The phrase "an effective amount" has been held to be indefinite when the claim fails to state the function which is to be achieved and more than one effect can

be implied from the specification or the relevant art. *In re Fredericksen* 213 F.2d 547, 102 USPQ 35 (CCPA 1954). The more recent cases have tended to accept a limitation such as "an effective amount" as being definite when read in light of the supporting disclosure and in the absence of any prior art which would give rise to uncertainty about the scope of the claim. In *Ex parte Skuballa*, 12 USPQ2d 1570 (Bd. Pat. App. & Inter. 1989), the Board held that a pharmaceutical composition claim which recited an "effective amount of a compound of claim 1" without stating the function to be achieved was definite, particularly when read in light of the supporting disclosure which provided guidelines as to the intended utilities and how the uses could be effected.

### 2173.05(d) Exemplary Claim Language ("for example," "such as") [R-1]

Description of examples or preferences is properly set forth in the specification rather than the claims. If stated in the claims, examples and preferences >may< lead to confusion over the intended scope of a claim. In those instances where it is not clear whether the claimed narrower range is a limitation, a rejection under 35 U.S.C. 112, second paragraph should be made. The examiner should analyze whether the metes and bounds of the claim are clearly set forth. Examples of claim language which have been held to be indefinite because the intended scope of the claim was unclear are:

- (A) "R is halogen, for example, chlorine";
- (B) "material such as rock wool or asbestos" *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1949);
- (C) "lighter hydrocarbons, such, for example, as the vapors or gas produced" *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949); and
- (D) "normal operating conditions such as while in the container of a proportioner" *Ex parte Steigerwald*, 131 USPQ 74 (Bd. App. 1961).

>The above examples of claim language which have been held to be indefinite are fact specific and should not be applied as *per se* rules. See MPEP § 2173.02 for guidance regarding when it is appropriate to make a rejection under 35 U.S.C. 112, second paragraph.<



In re Alton (CA FC) 37 USPQ2d 1578

**In re Alton**

**U.S. Court of Appeals Federal Circuit  
37 USPQ2d 1578**

**Decided February 5, 1996  
No. 94-1495**

**Headnotes**

**PATENTS**

**1. Practice and procedure in Patent and Trademark Office -- Prosecution --  
Declaration/Affidavits (§ 110.0913)**

**Patentability/Validity -- Specification -- Written description (§ 115.1103)**

Patent examiner erred by viewing declaration of person skilled in art as opinion evidence addressing question of law rather than question of fact, since declaration attempted to shed light on question of whether specification adequately described subject matter of application claim, since that question is one of fact, and since declaration, rather than asserting opinion on patentability of claimed human gamma interferon analog, offers factual evidence in attempt to explain why one of ordinary skill would have understood specification to describe particular analog claimed.

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**2. Practice and procedure in Patent and Trademark Office -- Prosecution --  
Declaration/Affidavits (§ 110.0913)**

**Patentability/Validity -- Specification -- Written description (§ 115.1103)**

Patent examiner erred by dismissing declaration of person skilled in art without adequate explanation of how declaration failed to overcome prima facie case for rejection on ground that application did not provide adequate written description of subject matter in claim for human gamma interferon analog, since statement in examiner's answer that specification encompasses substantial number of possible analogs does not refute thrust of declaration, which explains why one of ordinary skill in art would have realized that applicants had possession of one particular analog on their claimed filing date.

**Case History and Disposition:**

Appeal from the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences.

Patent application of Norman K. Alton, Mary A. Peters, Yitzhak Tabinski, and David L. Snitman, serial no. 06/483,451, filed April 15, 1983, which is continuation-in-part of application filed May 6, 1983, now abandoned. From decision upholding examiner's rejection of application claim 70 for failure to comply with written description requirement of 35 USC 112, applicants appeal. Vacated and remanded.

**Attorneys:**

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Scott A. Chambers, associate solicitor; Nancy J. Link, solicitor; Albin F. Drost, deputy solicitor, and Richard Torczon, associate solicitor, Arlington, Va., for appellee.

**Judge:**

Before Michel, circuit judge, Friedman, senior circuit judge, and Schall, circuit judge.

**Opinion Text**

**Opinion By:**

Schall, J.



Appellants Norman K. Alton, et al. ("Alton"), appeal the ruling of the United States Patent and Trademark Office Board of Patent Appeals and Interferences ("Board") in Appeal No. 94-3098. In its decision, the Board held that the specification of application serial number 06/483,451 ("the '451 application") did not provide adequate written descriptive support for the amino acid sequence of human gamma interferon ("IFN- $\gamma$ ") described in claim 70. We vacate the decision and remand the case to the Board for further proceedings.

## BACKGROUND I.

IFN- $\gamma$  is a protein secreted by cells in the human immune system to stimulate immunological activity. 1 Patrick W. Gray et al., *Expression of Human Immune Interferon cDNA in E. Coli and Monkey Cells*, 295 *Nature* 503 (1982). IFN- $\gamma$  is believed useful because it activates macrophages, which are a class of cells in the immune system. Bruce Alberts et al., *Molecular Biology of the Cell* 1048, 1049 (2d ed. 1989). IFN- $\gamma$  is composed of a sequence of 146 amino acids. 2 The complete sequence is divided into four subunits. IFN- $\gamma$  polypeptides containing alterations in the naturally-occurring amino acid sequence are called "analogs."

Claim 70 of the '451 application, set forth below, recites an analog of IFN- $\gamma$ :

[Met-<sup>1</sup>, des-Cys<sup>1</sup>, des-tyr<sup>2</sup>, des-cys<sup>3</sup>] IFN- $\gamma$  polypeptide produced by a DNA sequence coding therefor in a transformant organism, said product having substantially the characteristics of human immune interferon.

(brackets in original). The bracketed words at the beginning of the claim indicate how the claimed IFN- $\gamma$  differs from the natural version of IFN- $\gamma$ . 3 "Met," "cys," and "tyr" are abbreviations for three of the twenty amino acids; they stand for methionine, cysteine, and tyrosine, respectively. A positive superscripted number following the abbreviation of an amino acid indicates the position of that amino acid in the 146 amino acid chain that comprises IFN- $\gamma$ . For example, "tyr<sup>2</sup>" means that tyrosine is the second amino acid in the 146 amino acid chain. The designation "des" preceding the name of the amino acid indicates that that particular amino acid has been deleted and no amino acid has been substituted in its place. Therefore, "[des-cys<sup>1</sup>, des-tyr<sup>2</sup>, des-cys<sup>3</sup>]" means that the cysteine at position one of the amino acid chain has been removed, as has the

tyrosine at position two and the cysteine at position three. A negative superscripted number indicates that an amino acid has been added onto the beginning (the N-terminus) of the IFN-c sequence. Thus, "met-<sup>1</sup>" means that a methionine has been placed at the beginning of the IFN-c amino acid chain.

In sum, the analog of IFN-1 p recited in claim 70 has two characteristics that distinguish it from the natural version of IFN- IFN-c. First, as "[des-cys<sup>1</sup>, des-tyr<sup>2</sup>, des-cys<sup>3</sup>]" indicates, the first three amino acids -- cysteine, tyrosine, and cysteine -- of the natural 146 amino acid sequence have been deleted from the claimed IFN-c analog. These three amino acids are located on the fourth subunit ("IF-4") of the complete sequence. Second, methionine has been placed at the beginning of the amino acid sequence of the claimed analog.

The '451 application's specification contains twelve examples of IFN- c analogs. Of these, Example 5 is closest to the analog that is the subject of claim 70. Like claim 70, it discloses deletion of the first three amino acids and placement of methionine at the beginning of the amino acid sequence of IFN-c ("[met-<sup>1</sup>, des-cys<sup>1</sup>, des-tyr<sup>2</sup>, des- cys<sup>3</sup>]"). Unlike claim 70, however, Example 5 additionally discloses substitution of asparagine -- the eighty-first amino acid in the IFN- IFN- c chain -- with lysine, another amino acid ("lys<sup>81</sup>"). The eighty-first amino acid is located on the second subunit ("IF-2") of the IFN-c sequence.

## II.

The '451 application was filed April 15, 1983. It is a continuation-in-part of a parent application filed on May 6, 1982, and later abandoned. The examiner issued a final rejection of the claims of the '451 application as anticipated under 35 U.S.C. Section 102(e) and rendered obvious over the prior art under 35 U.S.C. Section 103.

Alton appealed the examiner's final rejection to the Board. On February 28, 1991, the Board reversed the examiner's section 102 and 103 rejections but rejected the claims on the new ground that the specification failed to describe adequately the subject matter of the claims, as required by 35 U.S.C. Section 112, Para. 1. The Board stated: "The closest analog to that claimed herein is described [in Example 5]. This particular analog, though similar to that claimed herein, does not constitute a description of the claimed analog."

Electing further prosecution pursuant to 37 C.F.R. 1.196(b), 4 Alton submitted to the examiner,

in response to the Board's section 112, Para. 1 rejection, a declaration by Dr. Randolph Wall (the "Wall declaration"). In due course, the examiner issued a final rejection on the same grounds as had the Board. Alton then requested reconsideration; the examiner denied the request and maintained his rejection ("final rejection").

Alton appealed the final rejection of claim 70 to the Board. The examiner filed his Answer and the Board sustained the section 112, Para. 1 rejection on June 21, 1994. In its decision, the Board held that "the specific polypeptide of claim 70 was not *described* in the original specification of application Serial No. 06/483,451." The Board adopted the examiner's dismissal of the Wall declaration, in which the examiner reasoned that the declaration was opinion evidence rather than factual evidence. The examiner stated, "Little weight is given an opinion affidavit on the ultimate legal question at issue." This appeal followed.

### DISCUSSION I.

The issue of whether a patent specification adequately describes the subject matter claimed is a question of fact. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). We review questions of fact arising from Board rejections under a clearly erroneous standard. *In re Caveney*, 761 F.2d 671, 674, 225 USPQ 1, 3 (Fed. Cir. 1985). We review questions of law *de novo*. *Electronic Design & Sales, Inc., v. Electronic Data Systems Corp.*, 954 F.2d 713, 715, 21 USPQ2d 1388, 1390 (Fed. Cir. 1992).

### II.

Alton contends that the Board committed clear error in holding that the '451 specification did not describe the subject matter of

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claim 70. Alton additionally argues that the Board erred in failing to give substantial weight to the Wall declaration.

The adequate written description requirement of 35 U.S.C. Section 112, Para. 1, provides that [t]he specification shall contain a *written description of the invention*, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make

and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(emphasis added).

The adequate written description requirement, which is distinct from the enablement and best mode requirements, 5 serves "to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him; how the specification accomplishes this is not material." *In re Wertheim* , 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976). In order to meet the adequate written description requirement, the applicant does not have to utilize any particular form of disclosure to describe the subject matter claimed, but "the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (citation omitted). Put another way, "the applicant must . . . convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention ." *Vas-Cath* , 935 F.2d at 1563-64, 19 USPQ2d at 1117. Finally, we have stated that "[p]recisely how close the original description must come to comply with the description requirement of section 112 must be determined on a case-by-case basis." *Eiselstein v. Frank* , 52 F.3d 1035, 1039, 34 USPQ2d 1467, 1470 (Fed. Cir. 1995) (quoting *Vas-Cath* , 935 F.2d at 1561, 19 USPQ2d at 1116).

As noted above, following the Board's decision of February 28, 1991, Alton elected further prosecution pursuant to 37 C.F.R. Section 1.196(b). In that context, Alton submitted the Wall declaration in response to the Board's section 112, Para. 1 rejection. In paragraph 9J of his declaration, Dr. Wall addressed the issue of whether Example 5 in the specification described what was claimed in claim 70: 6

J. The specific modifications of subunit IF-4 for deleting both cysteines and the intermediate tyrosine at amino acid positions 1, 2, and 3 are set out at page 50, lines 11 and 12, which describe modification of the IF-4 subunit (which contains a methionyl residue-specifying codon at position -1) to contain the codons,

5'-ATG CAG-3' 3'-TAC GTC-5'

in the amino acid specifying region. ATG is a codon specifying methionine; CAG is a codon specifying glutamine. Expression of a complete, four subunit, DNA sequence with this modification in subunit IF-4 operatively provides a polypeptide of claims 70. . . . It is my opinion that a skilled worker in molecular biology and the cloning and expression of genes,

would, in 1983, have understood the proposed modification [des-cys<sup>1</sup>, des-tyr<sup>2</sup>, des-cys<sup>3</sup>] to have been described independently of any suggestion to alter the arginine [sic: asparagine<sup>7</sup>] residue at position 81 of mature human immune interferon. While the specific analog including both the changes in the mature human immune interferon was described as being made and tested, that compound was noted to be an "example" of polypeptide analogs wherein cysteines were deleted for the purpose of facilitating isolation of analogs by destroying the possibility of intermolecular disulfide bridge formation. Modifying the residue at position 81 would have no effect on this property because neither arginine [sic: asparagine] nor lysine can

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participate in disulfide bridge formation. Moreover, changing to [sic] residue at position 81 would involve a modification in subunit IF-2, requiring an entirely separate series of manipulations of the complete DNA sequence to generate this different class of analog.

Among other things, the Wall declaration states that one of ordinary skill in the art in 1983 would have known, first, that a problem involved with isolating analogs was the capacity of the amino acid sequence to form bonds with itself through disulfide bridges, and second, that deletion of cysteines would eliminate this phenomenon. According to Dr. Wall, one of ordinary skill in the art would have understood the discussion in the specification of Example 5 to be offered as an illustration of the deletion of cysteines. Therefore, according to Dr. Wall, one of ordinary skill in the art, knowing that deleting the first three amino acids of the complete sequence would affect disulfide bridge formation but that the existence of lysine at position 81 would not, would have understood the specification to describe the two modifications independently. Also according to Dr. Wall, a second reason one of ordinary skill in the art would have understood the specification to describe the two modifications independently is that the first three amino acids are located on subunit IF-4, whereas the eighty-first amino acid is located on subunit IF-2.

In his final rejection, which was adopted by the Board, the examiner stated that the specification did not convey that Alton had possession of the subject matter of claim 70 as of April 15, 1983 -- the filing date of the '451 application. In support of the rejection, referring to Example 5, the examiner asserted that the only example in the specification that described deletion of the first

three amino acids and placement of methionine at the beginning of the amino acid sequence of IFN- $\gamma$  additionally described substitution of asparagine -- the eighty-first amino acid in the IFN- $\gamma$  chain -- with lysine, another amino acid. Turning to the Wall declaration, the examiner stated:

In order to support patentability of the claims Dr. Wall points to the same text of the specification as previously identified by the Board of Patent Appeals and Interferences as being insufficient. Importantly, Dr. Wall arrives at a conclusion which is opposite that determined by the Board. . . . In view of the previous discussion of the Board of Patent Appeals and Interferences and the evidence of record, this argument is not found to be persuasive. . . . The weight given to the 132 Declaration by Dr. Wall, in particular paragraph . . . 9J, depends on whether it presents allegations, opinions or facts. In this case the Declaration does not point to inherent support or evidence to support the conclusory statement in paragraph 9J. Little weight is given an opinion affidavit on the ultimate legal question at issue.

In short, the examiner rejected Dr. Wall's opinion that "a skilled worker in molecular biology and the cloning and expression of genes, would, in 1983, have understood the proposed modification to have been described independently of any suggestion to alter the arginine [sic] residue at position 81 of mature human immune interferon." The examiner maintained this position in his Answer. In his Answer, the examiner stated that

the Wall Declaration does not suggest that the written description in the specification supports an interferon-gamma which *must* have the claimed structure. Indeed, the number of possible interferon-gamma analogs encompassed by the written description of the invention is substantial and the specification does not lead to any compound which must have the claimed structure.

As already seen, the Board adopted as its own the examiner's response to Alton's arguments.

We express no opinion on the factual question of whether the specification adequately describes the subject matter of claim 70. 9 We do, however, hold that the examiner's final rejection and Answer contained two errors: (1) viewing the Wall declaration as opinion evidence addressing a question of law rather than a question of fact; and (2) the summary dismissal of the declaration, without an adequate explanation of why the declaration failed to rebut the Board's prima facie case of inadequate description.

### III.

#### A. *The Examiner Erred by Mistaking a Question of Fact for a Question of Law*

As seen above, in his final rejection, the examiner stated that the weight given to Dr. Wall's declaration

depends on whether it presents allegations, opinions or facts. In this case the Declaration does not point to inherent support or evidence to support the conclusory statement in paragraph 9J. Little weight is given an opinion affidavit on the ultimate legal question at issue.

In his Answer, the examiner continued that

[i]t is apparently the " *opinion* " (emphasis added) of Dr. Wall that, as of the filing date of this application, one skilled in the art would have interpreted . . . the specification as specific guidance for a class of interferon analogs lacking the cys-tyr-cys residues at the amino terminus. . . . Little weight is given an opinion affidavit on the ultimate legal question at issue regarding written description for the invention now claimed.

[1] It is well settled that the question of whether a specification provides an adequate written description of the subject matter of the claims is an issue of fact. Therefore, the examiner was in error when he stated that the Wall declaration, which attempted to shed light on whether the '451 specification adequately described the subject matter of claim 70, addressed a legal issue.

Additionally, the examiner interpreted the Wall declaration as offering opinion evidence, rather than factual evidence, on the adequate written description issue. The Wall declaration's assertion that "[m]odifying the residue at position 81 would have no effect on [disulfide bridge formation] because neither [asparagine] nor lysine can participate in disulfide bridge formation" is a factual statement, however. So too is the statement that changing the amino acid at position 81 would involve a modification in subunit IF-2, "requiring an entirely separate series of manipulations of the complete [amino acid] sequence to generate this different class of analog." We do not read the declaration as asserting an opinion on the patentability of the claimed IFN-c analog. Rather, the declaration is offering factual evidence in an attempt to explain *why* one of ordinary skill in the art would have understood the specification to describe the modification involving the deletion of the first three amino acids independently of the modification at position 81. Dr. Wall's use of the words "it is my opinion" to preface what someone of ordinary skill in the art would have known does not transform the factual statements contained in the declaration

into opinion testimony. 10 Consequently, the examiner's dismissal of the declaration on the grounds that "[l]ittle weight is given an opinion affidavit on the ultimate legal question at issue" was error.

*B. The Examiner Erred by Failing to Articulate Adequate Support for the Rejection*

The examiner also erred by dismissing the Wall declaration without an adequate explanation of how the declaration failed to overcome the prima facie case initially established by the Board -- the rejection on the ground that the application failed to describe the subject matter of claim 70. The examiner (or the Board, if the Board is the first body to raise a particular ground for rejection) "bears the initial burden . . . of presenting a prima facie case of unpatentability." *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). Insofar as the written description requirement is concerned, that burden is discharged by "presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims." *Wertheim*, 541 F.2d at 263, 191 USPQ at 97. Thus, the burden placed on the examiner varies, depending upon what the applicant claims. If the applicant claims embodiments of the invention that are completely outside the scope of the specification, then the examiner or Board need only establish this fact to make out a prima facie case. *Id.* at 263-64, 191 USPQ at 97. If, on the other hand, the specification contains a description of the claimed invention, albeit not *in ipso verbis* (in the identical words), then the examiner or Board, in order to meet the burden of proof, must provide reasons why one of ordinary skill in the art would not consider the description sufficient. *Id.* at 264, 191 USPQ at 98. Once the examiner or Board carries the burden of making out a prima facie case of unpatentability, "the burden of coming forward with evidence or argument shifts to the applicant." *Oetiker*, 977 F.2d at 1445, 24 USPQ2d at 1444. To overcome a prima facie case, an applicant must show that the invention as claimed is adequately described to

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one skilled in the art. "After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of the evidence with due consideration to persuasiveness of argument." *Id.* at 1445, 24 USPQ2d at 1444.

After claim 70 was first rejected on section 112, Para. 1 grounds, Alton submitted evidence to rebut the rejection in the form of the Wall declaration. 11 The Wall declaration contained



statements of fact directly addressing the issue of whether the specification adequately described the subject matter recited in claim 70. The purpose of the adequate written description requirement is to ensure that the inventor had possession of the claimed subject matter at the time the application was filed. If a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate written description requirement is met. For example, in *Ralston Purina Co. v. Far-Mar Co., Inc.*, 772 F.2d 1570, 1576, 227 USPQ 177, 180 (Fed. Cir. 1985), the trial court admitted expert testimony about known industry standards regarding temperature and pressure in "the art of extrusion of both farinaceous and proteinaceous vegetable materials." The effect of the testimony was to expand the breadth of the actual written description since it was apparent that the inventor possessed such knowledge of industry standards of temperature and pressure at the time the original application was filed. Similarly, the Wall declaration in essence attempts to expand the breadth of the specification by arguing that a person of ordinary skill in the art would have understood the two modifications in Example 5 of the specification to be described independently of each other and thus a description of both modifications would include a description of either separately.

The thrust of the examiner's response to the Wall declaration, in both the final rejection and the Answer, is that the specification must describe the precise analog claimed. This explains why the examiner stated that the Wall declaration was inadequate because it did not "suggest that the written description in the specification supports an interferon-gamma analog which *must* have the claimed structure." This argument, however, does not address the point that paragraph 9J of the Wall declaration attempts to make: that one of ordinary skill in the art would have understood the specification to describe the two modifications ([met - <sup>1</sup>, des-cys <sup>1</sup>, des-tyr <sup>2</sup>, des-cys <sup>3</sup>] and lys 8 <sup>1</sup>) independently and that the description of both modifications together would be relevant as an example of only one of those modifications ([met - <sup>1</sup>, des-cys <sup>1</sup>, des-tyr <sup>2</sup>, des-cys <sup>3</sup>]). Thus, according to the Wall declaration, the specification would be understood to describe the relevant modification ([met - <sup>1</sup>, des-cys <sup>1</sup>, des-tyr <sup>2</sup>, des-cys <sup>3</sup>]) without the irrelevant one (lys 8 <sup>1</sup>). Therefore, according to the Wall declaration, one of ordinary skill in the art would understand Alton to be in possession, in 1983, of the claimed subject matter, which contained the [met - <sup>1</sup>, des-cys <sup>1</sup>, des-tyr <sup>2</sup>, des-cys <sup>3</sup>] modification but not the

modification at position 81.

[2] The Wall declaration addresses why the claimed subject matter, although not identical to the analog described in the specification, was in Alton's possession. The statement in the examiner's answer that the number of possible analogs encompassed by the specification is substantial does not rebut the thrust of the Wall declaration because the Wall declaration explains why one of ordinary skill in the art would have realized that Alton had possession of one particular analog. In sum, in his final rejection and again in his Answer, the examiner dismissed the Wall declaration and provided only conclusory statements as to why the declaration did not show that a person skilled in the art would realize that Alton had possession of the claimed subject matter in 1983.

## CONCLUSION

First, by concluding that the Wall declaration addressed an issue of law instead of an issue of fact, and second, by failing to articulate adequate reasons to rebut the Wall declaration, the examiner and Board failed to consider the totality of the record for the purpose of issuing a final rejection and thus erred as a matter of law. We are not in a position, however, to determine whether the specification contained an adequate written description of the claimed IFN-c sequence. That determination requires, in the first instance, further proceedings in which the Wall declaration is addressed in a manner that is consistent with this opinion. The case is remanded to the Board for such further proceedings. See *In re Beaver*, 893 F.2d 329,

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13 USPQ2d 1409 (Fed. Cir. 1989) (vacating Board's decision for failing to review all the appealed claims in accordance with the relevant regulations).

## COSTS

Each side to pay its own costs. *VACATED and REMANDED*.

## ATTACHMENT A

1 Cyt- Tyr- Cys- Gln- Asp- Pro- Tyr- Val- Lys- Glu- Ala- Glu- Asn- Leu-  
 TGT TAC TGC CAG CAG CAA TAT GTA AAA GAA GCA GAA AAC CTT  
 20  
 Lys- Lys- Tyr- Phe- Asn- Ala- Gly- Ser- Asp- Val- Ala- Asp- Asn-  
 AAG AAA TAT TTT AAT GCA GGT CAT TCA GAT GTA GCG GAT AAT  
 30  
 Gly- Thr- Leu- Phe- Leu- Gly- Ile- Leu- Lys- Asn- Tyr- Lys- Glu- Glu-  
 CGA ACT CTT TTC TTA GGC ATT TTG AAG AAT TGG AAA GAG GAG  
 40  
 Ser- Asp- Arg- Lys- Ile- Met- Gln- Ser- Glu- Ile- Val- Ser- Phe- Tyr-  
 AGT GAC AGA AAA ATA ATG CAG AGC CAA ATT GTC TCC TTT TAC  
 50  
 Phe- Lys- Leu- Phe- Lys- Asn- Phe- Lys- Asp- Asp- Glu- Ser- Ile- Glu-  
 TTC AAA CTT TTT AAA AAC TTT AAA GAT GAC CAG AGC ATC CAA  
 60  
 Lys- Ser- Val- Glu- Thr- Ile- Lys- Glu- Asp- Met- Asn- Val- Lys- Phe-  
 AAG AGT GTG GAG ACC ATC AAG GAA GAC ATG AAT GTC AAG TTT  
 70  
 Phe- Asn- Ser- Asn- Lys- Lys- Lys- Arg- Asp- Asp- Phe- Glu- Lys- Leu-  
 TTC AAT AGC AAC AAA AAG AAA CGA GAT GAC TTC GAA AAG CTG  
 80  
 Thr- Asn- Tyr- Ser- Val- Thr- Asp- Leu- Asn- Val- Glu- Arg- Lys- Ala-  
 ACT AAT TAT TCG GTA ACT GAC TTG AAT GTC CAA CGC AAA GCA  
 90  
 Ile- His- Glu- Leu- Ile- Glu- Val- Met- Ala- Glu- Leu- Ser- Pro- Ala-  
 ATA CAT GAA CTC CTC ATC CAA ATG GCT GAA CTG TCG CAA GCA  
 100  
 Ala- Lys- Thr- Gly- Lys- Arg- Lys- Lys- Ser- Glu- Met- Leu- Phe- Glu-  
 OCT AAA ACA GGG AAG CGA AAA AGG AGT CAG ATG CTG TTT CAA  
 110  
 120  
 130  
 140  
 150

## Footnotes

Footnote 1. We understand the parties to be in agreement on the facts regarding the technology in this case.

Footnote 2. Amino acids, of which there are twenty, are small organic molecules. Benjamin Lewin, *Genes V* 11 (1994). Amino acids combine in linear chains to form proteins. *Id.* at 14. A protein is sometimes referred to as a polypeptide.

Footnote 3. The 146-amino acid sequence of the IFN-c analog recited in claim 70 is attached to this opinion.

Footnote 4. 37 C.F.R. Section 1.196(b) (1994) states:

When the Board of Patent Appeals and Interferences makes a new rejection of an appealed claim, the appellant may . . . submit . . . a showing of facts . . . and have the matter reconsidered by the examiner in which event the application will be remanded to the examiner. The statement shall be binding upon the examiner unless an amendment or showing of facts not previously of record be made which, in the opinion of the examiner, overcomes the new ground for rejection stated in the decision. Should the examiner again reject the application the applicant may again

appeal to the Board of Patent Appeals and Interferences.

Footnote 5. In order to be considered enabling, a patent must give persons of ordinary skill in the relevant art enough information to practice the invention disclosed in the specification without undue experimentation. *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984). The best mode requirement mandates that the inventor disclose the best mode known to him or her at the time the patent application is filed. *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1535, 3 USPQ2d 1737, 1745 (Fed. Cir.), *cert. denied*, 484 U.S. 954 (1987).

Footnote 6. The parties do not dispute that Dr. Wall has the requisite skill in the art.

Footnote 7. We understand the parties to be in agreement that recitation in the Wall declaration of the amino acid "arginine," instead of "asparagine," was a typographical error.

Footnote 8. Cysteines contain a sulfur atom. The sulfur atom of a cysteine in an amino acid chain can bond to the sulfur atom in a second cysteine at another location in the same amino acid sequence. Benjamin Lewin, *Genes V* 14 (1994). The resulting cysteine-cysteine bond, known as a disulfide bridge, causes the amino acid chain to bend back on itself. *Id.*

Footnote 9. *See Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) ("If a conception of a DNA requires a precise definition, such as by structure, formula, chemical name, or physical properties, . . . then a description also requires that degree of specificity.").

Footnote 10. In any event, we are aware of no reason why opinion evidence relating to a fact issue should not be considered by an examiner. *See Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 294, 227 USPQ 657, 665 (Fed. Cir. 1985), *cert. denied*, 475 U.S. 1017 (1986).

Footnote 11. We are satisfied that the Board met its prima facie case of establishing lack of adequate written description in its February 28, 1991 decision by discussing Example 5 of the specification, in which both modifications appeared together.

- End of Case -





Full Text of Cases (USPQ2d)

Fiers v. Revel (CA FC) 25 USPQ2d 1601

## **Fiers v. Revel**

**U.S. Court of Appeals Federal Circuit  
25 USPQ2d 1601**

**Decided January 19, 1993  
Nos. 92-1170, -1171**

### **Headnotes**

#### **PATENTS**

**1. Patentability/Validity -- Date of invention -- Conception (§ 115.0403)**

#### **JUDICIAL PRACTICE AND PROCEDURE**

**Procedure -- Judicial review -- Standard of review -- Patents (§ 410.4607.09)**

Conception is question of law, reviewed de novo on appeal, and if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated; thus, regardless of complexity or simplicity of method of isolation employed, conception of DNA sequence, like conception of any chemical substance, requires definition of that substance other than by its functional utility.

**PATENTS**

**2. Patentability/Validity -- Date of invention -- Conception (§ 115.0403)**

**Patent construction -- Claims -- Process (§ 125.1309)**

Conception may occur if inventor is able to define DNA sequence by its method of preparation, but only if DNA is claimed by that method; conception of substance claimed per se, without reference to process, requires conception of its structure, name, formula, or definitive chemical or physical properties, and existence of workable method of preparation therefore cannot establish conception of subject matter of interference count in question, which is DNA sequence, having particular biological activity or function, claimed without reference to process.

**3. Patentability/Validity -- Specification -- Written description (§ 115.1103)**

**JUDICIAL PRACTICE AND PROCEDURE**

**Procedure -- Judicial review -- Standard of review -- Patents (§ 410.4607.09)**

Compliance with written description requirement of 35 USC 112 is question of fact, reviewed on appeal for clear error; interference party is entitled to benefit of earlier-filed foreign application only if specification satisfies description requirement by reasonably conveying to artisan that party had possession of claimed subject matter at time of application.

**PATENTS**

**4. Practice and procedure in Patent and Trademark Office -- Interference -- Counts (§ 110.1703)**

**Patentability/Validity -- Specification -- Written description (§ 115.1103)**

Specification containing statement that claimed DNA sequence is part of invention, and reference to potential method for isolating sequence, does not satisfy written description requirement of 35 USC 112, since specification does not describe DNA itself, nor even demonstrate that disclosed method would actually produce DNA in question, and since application therefore does not demonstrate that inventor had possession of claimed DNA; contention that correspondence between language of interference count and language in specification is sufficient to satisfy written description requirement is thus unpersuasive, since none of that language particularly describes DNA sequence in interference.

**5. Practice and procedure in Patent and Trademark Office -- Interference -- Counts (§ 110.1703)**



**Patentability/Validity -- Date of invention -- Conception (§ 115.0403)**

**Patentability/Validity -- Specification -- Written description (§ 115.1103)**

Disclosure sufficient to satisfy written description requirement of 35 USC 112 for claimed DNA sequence must have same degree of specificity as disclosure which demonstrates conception, and must therefore include precise definition of DNA, such as by structure, formula, chemical name, or physical properties; interference count at issue, which purports to cover all DNA sequences that code for particular interferon, is analogous to single means claim, which has been held not to comply with Section 112, and thus language claiming all DNA sequences which achieve particular result, without defining what means will do so, is not in compliance with description requirement, even if language corresponds to that of count.

**6. Patentability/Validity -- Specification -- Enablement (§ 115.1105)**

**JUDICIAL PRACTICE AND PROCEDURE**

**Procedure -- Judicial review -- Standard of review -- Patents (§ 410.4607.09)**

Enablement is question of law that is reviewed de novo on appeal; enablement requirement of 35 USC 112 is satisfied if application contains description that enables one skilled in art to make and use claimed invention.

**PATENTS**

**7. Practice and procedure in Patent and Trademark Office -- Interference -- In general (§ 110.1701)**

**Practice and procedure in Patent and Trademark Office -- Interference -- Burden of proof (§ 110.1707)**

**Patentability/Validity -- Specification -- Enablement (§ 115.1105)**

Prevailing party in interference that did not produce extrinsic evidence of enablement did not, thereby, fail to prove that application is enabling, since party asserting failure to comply with 35 USC 112 bears burden of persuasion on that issue, and since prevailing party therefore had no further burden to submit extrinsic evidence of enablement once examiner accepted sufficiency of specification; opposing party was not deprived of opportunity to challenge prevailing party's entitlement to Japanese application filing date, even if opposer had no opportunity to cross-examine due to prevailing party's election to stand on filing date, since opposing party had other opportunities, including during motion period, to make such challenge.

**Case History and Disposition:**

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Appeal from the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences.

Three-way patent interference proceeding (no. 101,096), between Haruo Sugano, Masami Muramatsu, and Tadatsugu Taniguchi (application filed Oct. 27, 1980), Walter C. Fiers (application filed April 3, 1981), and Michel Revel and Pierre Tiollais (application filed Sept. 28, 1982). From decision awarding priority of invention (DNA which codes for a human fibroblast interferon-beta polypeptide) to Sugano, et al., Fiers and Revel, et al. appeal. Affirmed.

**Attorneys:**

David J. Lee, James F. Haley, Jr., and Ivor R. Elrifi, of Fish & Neave, New York, N.Y.; Roger L. Browdy, of Browdy & Neimark, Washington, D.C., for appellants.

Nels T. Lippert, of White & Case, New York, for appellees.

**Judge:**

Before Cowen, senior circuit judge, and Michel and Lourie, circuit judges.

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**Opinion Text**

**Opinion By:**

Lourie, J.

Walter C. Fiers, Michel Revel, and Pierre Tiollais appeal from the June 5, 1991 decision of the Patent and Trademark Office Board of Patent Appeals and Interferences, awarding priority of invention in a three-way interference proceeding, No. 101,096, to Haruo Sugano, Masami Muramatsu, and Tadatsugu Taniguchi (Sugano). We affirm.

## BACKGROUND

This interference among three foreign inventive entities relates to the DNA 1 which

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codes for human fibroblast beta-interferon ( $\beta$ -IF), a protein that promotes viral resistance in human tissue. It involves a single count which reads:

A DNA which consists essentially of a DNA which codes for a human fibroblast interferon-beta polypeptide.

The parties filed U.S. patent applications as follows: Sugano on October 27, 1980, Fiers on April 3, 1981, and Revel and Tiollais (Revel) on September 28, 1982. 2 Sugano claimed the benefit of his March 19, 1980 Japanese filing date, Revel claimed the benefit of his November 21, 1979 Israeli filing date, and Fiers sought to establish priority under 35 U.S.C. Section 102(g) based on prior conception coupled with diligence up to his British filing date on April 3, 1980.3

Sugano's Japanese application disclosed the complete nucleotide sequence of a DNA coding for  $\beta$ -IF and a method for isolating that DNA. 4 Revel's Israeli application disclosed a method for isolating a fragment of the DNA coding for  $\beta$ -IF as well as a method for isolating messenger RNA (mRNA) coding for  $\beta$ -IF, but did not disclose a complete DNA sequence coding for  $\beta$ -IF. 5 Fiers, who was working abroad, based his case for priority on an alleged conception either in September 1979 or in January 1980, when his ideas were brought into the United States, coupled with diligence toward a constructive reduction to practice on April 3, 1980, when he filed a British application disclosing the complete nucleotide sequence of a DNA coding for  $\beta$ -IF. According to Fiers, his conception of the DNA of the count occurred when two American scientists, Walter Gilbert and Phillip Sharp, to whom he revealed outside of the United States a proposed method for isolating DNA coding for  $\beta$ -IF, brought the protocol back to the United States. 6 Fiers submitted affidavits from Gilbert and Sharp averring that, based on Fiers' proposed protocol, one of ordinary skill in the art would have been able to isolate  $\beta$ -IF DNA without undue experimentation. 7 On February 26, 1980, Fiers' patent attorney brought into the United States a draft patent application disclosing Fiers' method, but not the nucleotide sequence for the DNA.

The Board awarded priority of invention to Sugano, concluding that (1) Sugano was entitled to the benefit of his March 19, 1980 Japanese filing date, 8 (2) Fiers was entitled to the benefit of his April 3, 1980 British filing date, but did not prove conception of the DNA of the count prior to that date, and (3) Revel was not entitled to the benefit of his November 21, 1979 Israeli filing date.

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The Board based its conclusions on the disclosure or failure to disclose the complete nucleotide sequence of a DNA coding for  $\beta$ -IF.

### **DISCUSSION      *Fiers' Case for Priority***

The Board held that Fiers failed to establish conception in the United States prior to his April 3, 1980 British filing date. Specifically, the Board determined that Fiers' disclosure of a method for isolating the DNA of the count, along with expert testimony that his method would have enabled one of ordinary skill in the art to produce that DNA, did not establish conception, since "success was not assured or certain until the [ $\beta$ -IF] gene was in fact isolated and its sequence known." The Board relied on our opinion in *Amgen Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991), in which we addressed the requirements necessary to establish conception of a purified DNA sequence coding for a specific protein. Accordingly, the Board held that Fiers was entitled only to the benefit of his April 3, 1980 British application date because only that application disclosed the complete nucleotide sequence of the DNA coding for  $\beta$ -IF. That date was subsequent to Sugano's March 1980 Japanese priority date.

Fiers argues that the Board erroneously determined that *Amgen* controls this case. According to Fiers, the Board incorrectly interpreted *Amgen* as establishing a rule that a DNA coding for a protein cannot be conceived until one knows the nucleotide sequence of that DNA. Fiers argues that this court decided *Amgen* on its particular facts and that this case is distinguishable. Fiers' position is that we intended to limit *Amgen* to cases in which isolation of a DNA was attended by serious difficulties such as those confronting the scientists searching for the DNA coding for erythropoietin (EPO), *e.g.*, screening a genomic DNA library with fully degenerate probes. According to Fiers, his method could have been easily carried out by one of ordinary skill in the

art. 9 Fiers also argues that *Amgen* held that a conception of a DNA can occur if one defines it by its method of preparation. Fiers suggests that the standard for proving conception of a DNA by its method of preparation is essentially the same as that for proving that the method is enabling. Fiers thus urges us to conclude that since his method was enabling for the DNA of the count, he conceived it in the United States when Gilbert and Sharp entered the country with the knowledge of, and detailed notes concerning, Fiers' process for obtaining it.

[1] Conception is a question of law that we review *de novo*. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81, 87 (Fed. Cir. 1986) (citing *Barmag Barmer Maschinenfabrik AG v. Murata Machinery, Ltd.*, 731 F.2d 831, 837, 221 USPQ 561, 565 (Fed. Cir. 1984)). Although *Amgen* was the first case in which we discussed conception of a DNA sequence coding for a specific protein, we were not writing on a clean slate. We stated:

Conception does not occur unless one has a mental picture of the structure of the chemical, or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property, *e.g.*, encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property. We hold that when an inventor is unable to envision the detailed chemical structure of the gene so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, *i.e.*, until after the gene has been isolated.

927 F.2d at 1206, 18 USPQ2d at 1021. We thus determined that, irrespective of the complexity or simplicity of the method of isolation employed, conception of a DNA, like conception of any chemical substance, requires a definition of that substance other than by its functional utility.

[2] Fiers' attempt to distinguish *Amgen* therefore is incorrect. We also reject Fiers' argument that the existence of a workable method for preparing a DNA establishes conception of that material. Our statement in *Amgen* that conception may occur, *inter alia*, when one is able to define a chemical by its method of preparation requires that the

DNA be claimed by its method of preparation. We recognized that, in addition to being

claimable by structure or physical properties, a chemical material can be claimed by means of a process. A product-by-process claim normally is an after-the-fact definition, used after one has obtained a material by a particular process. Before reduction to practice, conception only of a process for making a substance, without a conception of a structural or equivalent definition of that substance, can at most constitute a conception of the substance claimed as a process. Conception of a substance claimed *per se* without reference to a process requires conception of its structure, name, formula, or definitive chemical or physical properties.

The present count is to a product, a DNA which codes for  $\beta$ -IF; it is a claim to a product having a particular biological activity or function, and in *Amgen*, we held that such a product is not conceived until one can define it other than by its biological activity or function. The difficulty that would arise if we were to hold that a conception occurs when one has only the idea of a compound, defining it by its hoped-for function, is that would-be inventors would file patent applications before they had made their inventions and before they could describe them. That is not consistent with the statute or the policy behind the statute, which is to promote disclosure of inventions, not of research plans. While one does not need to have carried out one's invention before filing a patent application, one does need to be able to describe that invention with particularity.

Fiers has devoted a considerable portion of his briefs to arguing that his method was enabling. The issue here, however, is conception of the DNA of the count, not enablement. Enablement concerns teaching one of ordinary skill in the art how to practice the claimed invention. See 35 U.S.C. Section 112 (1988); *Amgen*, 927 F.2d at 1212, 18 USPQ2d at 1026. Since Fiers seeks to establish priority under section 102(g), the controlling issue here is whether he conceived a DNA coding for  $\beta$ -IF, not whether his method was enabling.

We conclude that the Board correctly decided that conception of the DNA of the count did not occur upon conception of a method for obtaining it. Fiers is entitled only to the benefit of his April 3, 1980 British filing date, since he did not conceive the DNA of the count under section 102(g) prior to that date.

### ***Revel's Case for Priority***

Revel bears the burden of proving entitlement to the benefit of his earlier-filed Israeli application date. *Utter v. Hiraga*, 845 F.2d 993, 998, 6 USPQ2d 1709, 1713 (Fed. Cir. 1988). To meet this burden, Revel must prove that his application meets the requirements of 35 U.S.C.

Section 112, first paragraph, *Bigham v. Godtfredsen*, 857 F.2d 1415, 1417, 8 USPQ2d 1266, 1268 (Fed. Cir. 1988) (citing *Cross v. Iuzika*, 753 F.2d 1040, 1043, 224 USPQ 739, 741 (Fed. Cir. 1985)), which provides in pertinent part:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same. . . .

Revel thus must show that the Israeli application contains a written description of the DNA of the count and that it is enabling.

The Board held that Revel's Israeli application did not contain a written description of a DNA coding for  $\beta$ -IF since it did not disclose the nucleotide sequence or "an intact complete gene." The Board, in denying Revel's request for reconsideration, rejected the argument that it is only necessary to show some correspondence between the language in the count and language in the Israeli application to satisfy the written description requirement. The Board stated:

Moreover, what is needed to meet the description requirement will necessarily vary depending on the nature of the invention claimed. The test for sufficiency of support is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." As is apparent from our decision, we found the description in Revel's Israeli application inadequate to reasonably convey to the artisan that Revel was in possession of the invention of beta-interferon DNA [citations omitted].

Relying on *Amgen*, the Board concluded that the Israeli application was not enabling since Revel had not yet conceived the DNA of the count and " [l]ogically, one cannot . . . enable an invention that has not been conceived." Slip op. at 13.

Revel argues that the disclosure of his Israeli application satisfies the written description requirement because it contains language of similar scope and wording to that of the count. Revel cites the following passages from the Israeli application:

The invention thus concerns also said purified m-RNAs which comprises normally up to 900-1000 nucleotides. . . . In the



same manner *it also concerns the corresponding c-DNA which can be obtained by transcription of said RNAs* [emphasis added]; It is a further object of the present invention to provide a process for the isolation of genetic material (DNA) containing the nucleotide sequence coding for interferon in human cells.

Revel points to a claim in the original Israeli application that corresponds substantially to the language of the count. 10 According to Revel, since the language of the count refers to a DNA and not to a specific sequence, the specification need not describe the sequence of the DNA in order to satisfy the written description requirement. Revel thus urges that only similar language in the specification or original claims is necessary to satisfy the written description requirement.

[3] We disagree. Compliance with the written description requirement is a question of fact which we review for clear error. See *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991); *Utter*, 845 F.2d at 998, 6 USPQ2d at 1714. On reconsideration, the Board correctly set forth the legal standard for sufficiency of description: the specification of Revel's Israeli application must "reasonably convey [ ] to the artisan that the inventor had possession at that time of the . . . claimed subject matter." Slip op. at 3 (citing *Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1117).

[4] An adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself. Revel's specification does not do that. Revel's application does not even demonstrate that the disclosed method actually leads to the DNA, and thus that he had possession of the invention, since it only discloses a clone that might be used to obtain *mRNA* coding for  $\beta$ -IF. 11 A bare reference to a DNA with a statement that it can be obtained by reverse transcription is not a description; it does not indicate that Revel was in possession of the DNA. Revel's argument that correspondence between the language of the count and language in the specification is sufficient to satisfy the written description requirement is unpersuasive when none of that language particularly describes the DNA.

[5] As we stated in *Amgen* and reaffirmed above, such a disclosure just represents a wish, or arguably a plan, for obtaining the DNA. If a conception of a DNA requires a precise definition, such as by structure, formula, chemical name, or physical properties, as we have held, then a description also requires that degree of specificity. To paraphrase the Board, one cannot describe what one has not conceived.

Because the count at issue purports to cover all DNAs that code for  $\beta$ -IF, it is also analogous to a single means claim, which has been held not to comply with the first paragraph of section 112. See *In re Hyatt*, 708 F.2d 712, 218 USPQ 195, 197 (Fed. Cir. 1983) ("the enabling disclosure of the specification [must] be commensurate in scope with the claim under consideration.") Claiming all DNA's that achieve a result without defining what means will do so is not in compliance with the description requirement; it is an attempt to preempt the future before it has arrived.

The Board's determination that the Israeli application does not contain a written description of a DNA coding for  $\beta$ -IF was thus not clearly erroneous. The Board correctly determined that Revel is not entitled to the benefit of his November 1979 Israeli application since it fails to satisfy the written description requirement of section 112.12

### ***Sugano's Case for Priority***

The Board held that Sugano established entitlement to his March 19, 1980 Japanese filing date because the disclosure of his Japanese application contains the complete and correct sequence of the DNA which codes for  $\beta$ -IF, along with a detailed disclosure of the method used by Sugano to obtain that DNA. The Board rejected Fiers' argument that Sugano's March 1980 application is not enabling, since Fiers presented only attorney argument that was "unsupported by competent

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evidence, entitled to little or no weight and [was] unpersuasive in any event." Slip op. at 12. Fiers argues that Sugano failed to prove that his application is enabling because he did not produce extrinsic evidence showing enablement. Fiers also argues that the Board erroneously imposed a burden on him to show that Sugano's application is not enabling when, in fact, Fiers had no right to submit rebuttal evidence once Sugano elected to rely solely on his Japanese application.

[6] [7] Enablement is a question of law that we review *de novo*. *Amgen*, 927 F.2d at 1212, 18 USPQ2d at 1026. Enablement requires that the application " 'contain a description that enables one skilled in the art to make and use the claimed invention.' " *Id.*, (citing *Atlas Powder Co. v. E.I. duPont De Nemours & Co.*, 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984)). " [A] specification disclosure which contains a teaching of the manner and process of making and

using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must* be taken as in compliance with the enabling requirement of the first paragraph of Section 112 *unless* there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." *In re Marzocchi*, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971). "[A]ny party making the assertion that a U.S. patent specification or claims fails, for one reason or another, to comply with Section 112 bears the burden of persuasion in showing said lack of compliance." *Weil v. Fritz*, 601 F.2d 551, 555, 202 USPQ 447, 450 (CCPA 1979). Thus, once the examiner accepted the sufficiency of Sugano's specification, Sugano had no further burden to prove by extrinsic evidence that his application was enabling; the Board correctly determined that it was Fiers (or Revel) who then had to prove that Sugano's application was not enabling. Even if Fiers had no opportunity to cross-examine Sugano because Sugano elected to stand on his filing date, Fiers had other opportunities, including during the motion period, to challenge Sugano's entitlement to his Japanese application filing date. Thus, he did not lack opportunity to challenge. We conclude that Sugano is entitled to rely on his disclosure as enabling since it sets forth a detailed teaching of a method for obtaining a DNA coding for  $\beta$ -IF and the Board did not err in determining that Fiers presented no convincing evidence impeaching the truth of the statements in Sugano's patent specification. We also conclude that Sugano's application satisfies the written description requirement since it sets forth the complete and correct nucleotide sequence of a DNA coding for  $\beta$ -IF and thus "convey [s] with reasonable clarity to those skilled in the art that, as of the filing date sought, [Sugano] was in possession of the [DNA coding for  $\beta$ -IF]." *See Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1117. The Board correctly determined that Sugano's March 19, 1980 Japanese application satisfies the requirements of section 112, first paragraph, and that Sugano thus met his burden to establish entitlement to that filing date.

### CONCLUSION

The Board correctly awarded priority of invention to Sugano. Accordingly, the decision of the Board is

**AFFIRMED.**

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Footnotes

Footnote 1. DNA is deoxyribonucleic acid, a generic term encompassing the many chemical materials that genetically control the structure and metabolism of living things.

Footnote 2. Revel assigned his application to Yeda Research and Dev. Co. Ltd. The real party in interest in the Fiers application has been indicated to be Biogen, Inc. The real party in interest in the Sugano application has been indicated to be Juridical Foundation, Japanese Foundation for Cancer Research.

Footnote 3. 35 U.S.C. Section 102 provides in pertinent part:

A person shall be entitled to a patent unless . . .

(g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

Footnote 4. Sugano's method involved the preparation of two populations of radioactivity-labelled cDNA probes prepared from the mRNA of fibroblast cells. One population of probes was prepared from the mRNA of induced fibroblast cells and the other population from the mRNA of non-induced cells. These probes were then exposed to a cDNA library prepared from induced cells, and the clones that only hybridized with the first probe were selected. The selected clones were then used as probes to select the full-length DNA sequence encoding  $\beta$ -IF, which was then sequenced.

Footnote 5. Revel's method involved preparing a cDNA library of clones from the mRNA of cells induced to produce  $\beta$ -IF, screening each clone for hybridization to mRNA from induced cells, eluting the hybridized mRNA, and assaying the eluted mRNAs for  $\beta$ -IF activity.

Footnote 6. Fiers presented his protocols and progress to date toward isolating DNA coding for  $\beta$ -IF at a September 21, 1979 meeting in Paris at which Sharp and Gilbert were present. Sharp and Gilbert returned to the United States on September 23 and 24, respectively. Fiers made a second presentation in Martinique on January 12, 1980. Gilbert and Sharp were both present and

returned to the United States on January 15 and 17, respectively. On March 25, 1980, Fiers disclosed by telephone to his patent attorney that he had determined the entire nucleotide sequence of a DNA coding for  $\beta$ -IF. Fiers presented that nucleotide sequence along with a protocol for preparing the complete DNA in Switzerland on March 28, 1980. Fiers and his attorney worked from March 31 until April 2 in Ghent drafting the final portion and claims of the British application that Fiers filed on April 3, 1980.

Footnote 7. Fiers' proposed protocol involved preparing a cDNA library from the mRNA of cells induced to produce  $\beta$ -IF mRNA, and screening the cDNA library for a cDNA that, when introduced into a cell, would cause it to display  $\beta$ -IF activity.

Footnote 8. Sugano also claimed the benefit of an October 30, 1979 Japanese filing date which the Board denied. Sugano does not challenge that determination on appeal.

Footnote 9. Fiers' method involved screening a cDNA library which he maintains is smaller and less complex than a genomic DNA library. Fiers also contends that his screening techniques were routine to those skilled in the art, while those skilled in the art lacked experience screening with fully degenerate probes. Fiers also notes that, in contrast to the situation with EPO in which erroneous amino acid sequence information had been published, the first thirteen amino acids of  $\beta$ -IF were known to the art.

Footnote 10. Claim 22 of Revel's original Israeli application reads:

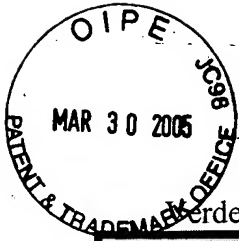
The DNA coding for a polypeptide having interferon activity insertable in a vector, such as plasmid PBR-322, and having up to 900-1000 nucleotides.

Footnote 11. According to Fiers, Revel's Israeli application also fails the written description requirement because the mRNA disclosed in the application encodes a protein weighing 23,000 daltons which is interleukin-6, not  $\beta$ -IF. The Board did not premise its decision on this point, and, since we determine that Revel's application does not describe the DNA of the count, we need not reach it either.

Footnote 12. In light of our disposition of the written description requirement question, we do not address whether Revel's Israeli application satisfies the enablement requirement.

- End of Case -





Verdegaal Brothers Inc. v. Union Oil Company of California (CA FC) 2 USPQ2d 1051

## **Verdegaal Brothers Inc. v. Union Oil Company of California**

**U.S. Court of Appeals Federal Circuit  
2 USPQ2d 1051**

**Decided March 12, 1987  
No. 86-1258**

### **Headnotes**

#### **PATENTS**

##### **1. Patentability/Validity -- Anticipation -- Prior art (§ 115.0703)**

Federal district court erred in denying patent infringement defendant's motion for judgment n.o.v., in view of evidence demonstrating that claims for making urea-sulfuric acid fertilizer, including claims that reaction be conducted in "heat sink" of recycled fertilizer to prevent high temperature buildup, were anticipated by prior art patent that specifically detailed process for making such urea-sulfuric acid products and that explicitly taught that base or "heel" of recycled

fertilizer can be used to make more of product, even if patentee of prior art did not recognize that heel functioned as heat sink, since heat sink property was inherently possessed by heel.

**Particular patents -- Fertilizers**

4,310,343, Verdegaal and Verdegaal, Process for Making Liquid Fertilizer, holding of validity and infringement reversed.

**Case History and Disposition:**

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Appeal from District Court for the Eastern District of California, Coyle, J.

Action by Verdegaal Brothers Inc., William Verdegaal, and George Verdegaal, against Union Oil Company of California, and Brea Agricultural Services Inc., for patent infringement. From decision denying defendants' motion for judgment notwithstanding the verdict, defendants appeal. Reversed.

**Attorneys:**

Andrew J. Belansky of Christie, Parker & Hale (David A. Dillard, with him on the brief), all of Pasadena, Calif., for appellants.

John P. Sutton of Limbach, Limbach & Sutton (Michael E. Dergosits, with him on the brief), all of San Francisco, Calif., for appellees.



**Judge:**

Before Markey, Chief Judge, and Davis and Nies, Circuit Judges.

**Opinion Text**

**Opinion By:**

Nies, Circuit Judge.

Union Oil Company of California and Brea Agricultural Services, Inc. (collectively Union Oil) appeal from a judgment of the United States District Court for the Eastern District of California, No. CV-F-83-68 REC, entered on a jury verdict which declared U.S. Patent No. 4,310,343 ('343), owned by Verdegaal Brothers, Inc., "valid" and claims 1, 2, and 4 thereof infringed by Union Oil. Union Oil's motion for judgment notwithstanding the verdict (JNOV) was denied. We reverse.

I

**BACKGROUND**

***The General Technology***

The patent in suit relates to a process for making certain known urea-sulfuric acid liquid fertilizer products. These products are made by reacting water, urea (a nitrogen-containing chemical), and sulfuric acid (a sulfur-containing chemical) in particular proportions. The nomenclature commonly used by the fertilizer industry refers to these fertilizer products numerically according to the percentages by weight of four fertilizer constituents in the following order: nitrogen, phosphorous, potassium, and sulfur. Thus, for example, a fertilizer containing 28% nitrogen, no phosphorous or potassium, and 9% sulfur is expressed numerically as 28-0-0-9.

***The Process of the '343 Patent***

The process disclosed in the '343 patent involves the chemical reaction between urea

and sulfuric acid, which is referred to as an exothermic reaction because it gives off heat. To prevent high temperature buildup, the reaction is conducted in the presence of a nonreactive, nutritive heat sink which will absorb the heat of reaction. Specifically, a previously-made batch of liquid fertilizer -- known as a "heel" -- can serve as the heat sink to which more reactants are added. Claims 1 and 2 are representative:

1. In a process for making a concentrated liquid fertilizer by reacting sulfuric acid and urea, to form an end product, the improvement comprising:
  - a. providing a non-reactive, nutritive heat sink, capable of dissipating the heat of urea and sulfuric acid, in an amount at least 5% of the end product,
  - b. adding water to the heat sink in an amount not greater than 15% of the end product,
  - c. adding urea to the mixture in an amount of at least 50% of the total weight of the end product,
  - d. adding concentrated sulfuric acid in an amount equal to at least 10% of the total weight of the end product.
2. The process of claim 1 wherein the heat sink is recycled liquid fertilizer.

### ***Procedural History***

Verdegaal brought suit against Union Oil in the United States District Court for the Eastern District of California charging that certain processes employed by Union Oil for making liquid fertilizer products infringed all claims of its '343 patent. Union Oil defended on the grounds of noninfringement and patent invalidity under 35 U.S.C. §§102, 103. The action was tried before a jury which returned a verdict consisting of answers to five questions. Pertinent here are its answers that the '343 patent was "valid" over the prior art, and that certain of Union Oil's processes infringed claims 1, 2, and 4 of the patent. None were found to infringe claims 3 or 5. Based on the jury's verdict, the district court entered judgment in favor of Verdegaal. Having unsuccessfully moved for a directed verdict under Fed. R. Civ. P. 50(a), Union Oil timely filed a motion under Rule 50(b) for JNOV seeking a judgment that the claims of the '343 patent were invalid under sections 102 and 103. The district court denied the motion without opinion.

II

## ISSUE PRESENTED

Did the district court err in denying Union Oil's motion for JNOV with respect to the validity of claims 1, 2, and 4 of the '343 patent?

### III

### *Standard of Review*

When considering a motion for JNOV a district court must: (1) consider all of the evidence; (2) in a light most favorable to the non-moving party; (3) drawing all reasonable inferences favorable to that party; (4) without determining credibility of the witnesses; and (5) without substituting its choice for that of the jury's in deciding between conflicting elements of the evidence. *Railroad Dynamics, Inc. v. A. Stucki Co.*, 727 F.2d 1506, 1512-13, 220 USPQ 929, 936 (Fed. Cir.), *cert. denied*, 469 U.S. 871 [ 224 USPQ 520 ] (1984); *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1546, 220 USPQ 193, 197 (Fed. Cir. 1983). A district court should grant a motion for JNOV only when it is convinced upon the record before the jury that reasonable persons could not have reached a verdict for the nonmoving party. *Railroad Dynamics*, 727 F.2d at 1513, 220 USPQ at 936; *Connell*, 722 F.2d at 1546, 220 USPQ at 197.

To reverse the district court's denial of the motion for JNOV, Union Oil must convince us that either the jury's factual findings are not supported by substantial evidence, or, if they are, that those findings cannot support the legal conclusions which necessarily were drawn by the jury in forming its verdict. *See Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 893, 221 USPQ 669, 673 (Fed. Cir.), *cert. denied*, 469 U.S. 857 [ 225 USPQ 792 ] (1984). *Railroad Dynamics*, 727 F.2d at 1512, 220 USPQ at 936. Substantial evidence is more than just a mere scintilla; it is such relevant evidence from the record taken as a whole as a reasonable mind might accept as adequate to support the finding under review. *Consolidated Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938); *Perkin-Elmer*, 732 F.2d at 893, 221 USPQ at 673; *SSIH Equip. S.A. v. U.S. Int'l Trade Comm'n*, 718 F.2d 365, 371 n.10, 218 USPQ 678, 684 n.10 (Fed. Cir. 1983). A trial court's denial of a motion for JNOV must stand unless the evidence is of such quality and weight that reasonable and fair-minded persons in the exercise of impartial judgment could not reasonably return the jury's verdict. *Envirotech Corp. v. Al George, Inc.*, 730 F.2d 753, 758, 221 USPQ 473, 477 (Fed. Cir. 1984).

Our precedent holds that the presumption of validity afforded a U.S. patent by 35

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U.S.C. § 282 requires that the party challenging validity prove the facts establishing invalidity by clear and convincing evidence. *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360, 220 USPQ 763, 770 (Fed. Cir.), *cert. denied*, 469 U.S. 821 [ 224 USPQ 520 ] (1984). Thus, the precise question to be resolved in this case is whether Union Oil's evidence is so clear and convincing that reasonable jurors could only conclude that the claims in issue were invalid. *See Perkin-Elmer*, 732 F.2d at 893, 221 USPQ at 673; *Railroad Dynamics*, 727 F.2d at 1511, 220 USPQ at 935.

### ***Anticipation***

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *See, e.g., Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 715, 223 USPQ 1264, 1270 (Fed. Cir. 1984); *Connell*, 722 F.2d at 1548, 220 USPQ at 198; *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 771, 218 USPQ 781, 789 (Fed. Cir. 1983), *cert. denied*, 465 U.S. 1026 [ 224 USPQ 520 ] (1984). Union Oil asserts that the subject claims of the '343 patent are anticipated under 35 U.S.C. § 102(e) 1 by the teachings found in the original application for U.S. Patent No. 4,315,783 to Stoller, which the jury was instructed was prior art.

From the jury's verdict of patent validity, we must presume that the jury concluded that Union Oil failed to prove by clear and convincing evidence that claims 1, 2, and 4 were anticipated by the Stoller patent. *See Perkin-Elmer*, 732 F.2d at 893, 221 USPQ at 673; *Railroad Dynamics*, 727 F.2d at 1516, 220 USPQ at 939. Under the instructions of this case, this conclusion could have been reached only if the jury found that the Stoller patent did not disclose each and every element of the claimed inventions. Having reviewed the evidence, we conclude that substantial evidence does not support the jury's verdict, and, therefore, Union Oil's motion for JNOV on the grounds that the claims were anticipated should have been granted.

The Stoller patent discloses processes for making both urea-phosphoric acid and urea-sulfuric acid fertilizers. Example 8 of Stoller specifically details a process for making 30-0-0-10 urea-sulfuric acid products. There is no dispute that Example 8 meets elements b, c, and d of

claim 1, specifically the steps of adding water in an amount not greater than 15% of the product, urea in an amount of at least 50% of the product, and concentrated sulfuric acid in an amount of at least 10% of the product. Verdegaal disputes that Stoller teaches element a, the step of claim 1 of "providing a non-reactive, nutritive heat sink." As set forth in claim 2, the heat sink is recycled fertilizer. 2

The Stoller specification, beginning at column 7, line 30, discloses:

Once a batch of liquid product has been made, it can be used as a base for further manufacture. This is done by placing the liquid in a stirred vessel of appropriate size, adding urea in sufficient quantity to double the size of the finished batch, adding any water required for the formulation, and slowly adding the sulfuric acid while stirring. Leaving a heel of liquid in the vessel permits further manufacture to be conducted in a stirred fluid mass.

This portion of the Stoller specification explicitly teaches that urea and sulfuric acid can be added to recycled fertilizer, i.e., a heel or base of previously-made product. Dr. Young, Union Oil's expert, so testified. Verdegaal presented no evidence to the contrary.

Verdegaal first argues that Stoller does not anticipate because in Stoller's method sulfuric acid is added *slowly*, whereas the claimed process allows for rapid addition. However, there is no limitation in the subject claims with respect to the rate at which sulfuric acid is added, and, therefore, it is inappropriate for Verdegaal to rely on that distinction. *See SSIH*, 718 F.2d at 378, 218 USPQ at 689. It must be assumed that slow addition would not change the claimed process in any respect including the function of the recycled material as a heat sink.

Verdegaal next argues that the testimony of Union Oil's experts with respect to what

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Stoller teaches could well have been discounted by the jury for bias. Discarding that testimony does not eliminate the reference itself as evidence or its uncontradicted disclosure that a base of recycled fertilizer in a process may be used to make more of the product.

[1] Verdegaal raises several variations of an argument, all of which focus on the failure of Stoller to explicitly identify the heel in his process as a "heat sink." In essence, Verdegaal maintains that because Stoller did not recognize the "inventive concept" that the heel functioned as a heat sink, Stoller's process cannot anticipate. This argument is wrong as a matter of fact and law. Verdegaal's own expert, Dr. Bahme, admitted that Stoller discussed the problem of high

temperature caused by the exothermic reaction, and that the heel could function as a heat sink. 3 In any event, Union Oil's burden of proof was limited to establishing that Stoller disclosed the same process. It did not have the additional burden of proving that Stoller recognized the heat sink capabilities of using a heel. Even assuming Stoller did not recognize that the heel of his process functioned as a heat sink, that property was inherently possessed by the heel in his disclosed process, and, thus, his process anticipates the claimed invention. See *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981); *In re Swinehart*, 439 F.2d 210, 212-13, 169 USPQ 226, 229 (CCPA 1971). The pertinent issues are whether Stoller discloses the process of adding urea and sulfuric acid to a previously-made batch of product, and whether that base would in fact act as a heat sink. On the entirety of the record, these issues could only be resolved in the affirmative.

On appeal Verdegaal improperly attempts to attack the status of the Stoller patent as prior art, stating in its brief:

Verdegaal also introduced evidence at trial that the Stoller patent is not prior art under 35 U.S.C. §§ 102(e)/103. Professor Chisum testified that the Stoller patent, in his opinion, was not prior art. . . . This conclusion finds support in *In re Wertheim*, 646 F.2d 527 [ 209 USPQ 554 ] (CCPA 1981), and 1 Chisum on Patents §3.07[3].

Appellee Brief at 27 (record cite omitted). Seldom have we encountered such blatant distortion of the record. A question about the status of the Stoller disclosure as prior art did arise at trial. Union Oil asserted that, even though the Stoller patent issued after the '343 patent, Stoller was prior art under section 102(e) as of its filing date which was well before the filing date of Verdegaal's application. Professor Chisum never testified that the Stoller patent was *not* prior art, but rather, stated that *he did not know* whether it was prior art. An excerpt from the pertinent testimony leaves no doubt on this point:

Q. (Mr. Sutton): And do you know whether the Stoller patent is prior art to the application of the Verdegaal patent?

A. (Prof. Chisum): I don't know that it is, no.

We find it even more incredible that Verdegaal would attempt to raise an issue with respect to the status of the Stoller patent given that the case was submitted to the jury with the instruction that the original Stoller patent application was prior art. 4 Verdegaal made no objection to that instruction below, and in its appeal briefs, the instruction is cavalierly ignored.

In sum, Verdegaal is precluded from arguing that the Stoller patent should not be considered

prior art. *See* Fed. R. Civ. P. 51; *Weinar v. Rollform Inc.*, 744 F.2d 797, 808, 223 USPQ 369, 375 (Fed. Cir. 1984), *cert. denied*, 105 S.Ct. 1844 (1985); *Bio-Rad Laboratories, Inc. v. Nicolet Instrument Corp.*, 739 F.2d 604, 615, 222 USPQ 654, 662 (Fed. Cir.), *cert. denied*, 469 U.S. 1038 (1984). 5

After considering the record taken as a whole, we are convinced that Union Oil established anticipation of claims 1, 2, and 4 by clear and convincing evidence and that no reasonable juror could find otherwise. Consequently, the jury's verdict on validity is unsupported by substantial evidence and

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cannot stand. Thus, the district court's denial of Union Oil's motion for JNOV must be reversed.

### **Conclusion**

Because the issues discussed above are dispositive of this case, we do not find it necessary to reach the other issues raised by Union Oil. 6 In accordance with this opinion, we reverse the portion of the judgment entered on the jury verdict upholding claims 1, 2, and 4 of the '343 patent as valid under section 102(e) and infringed.

**REVERSED**

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### **Footnotes**

Footnote 1. Section 102(e) provides:

A person shall be entitled to a patent unless--

....

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international

application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent

Footnote 2. Claim 4 is written in terms of approximate percentages of all reactants by weight of the end product. No argument is made that the process of claim 4 would result in a fertilizer product any different from that disclosed by Example 8 of Stoller.

Footnote 3. There is no dispute that the percentage of heel described in Stoller meets the percentage of heat sink required by the claims.

Footnote 4. The jury instruction read:

Stoller filed two patent applications -- an original application on October 30th, 1978, and a second on February 7th, 1980. Under the patent laws, the claims of the 343 patent are invalid if you find that the original application (Exhibit BL) anticipates the process claimed in the 343 patent.

Footnote 5. Union Oil also argues that Verdegaal's counsel misled the jury by its closing rebuttal argument:

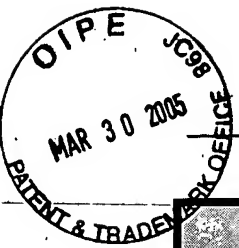
ut I think it's important to keep in mind that [Stoller] couldn't have been a prior patent because it issued a month after the Verdegaal patent had issued.

We disapprove of Verdegaal's tactic which would form the basis for a grant of a motion for a new trial but for our conclusion that outright reversal of the ruling on the motion for JNOV is in order.

Footnote 6. It should not be inferred that all of these issues were properly before us. Union Oil appears to assume that on appeal it may dispute the resolution of any *issue* which is denominated an "issue of law" even though it was not raised in its motion for JNOV. This is incorrect. *See Railroad Dynamics*, 727 F.2d at 1511, 220 USPQ at 934.

- End of Case -





In re Wertheim, et al., 191 USPQ 90 (CCPA 1976)

**In re Wertheim, et al.**

**(CCPA)  
191 USPQ 90**

**Decided Aug. 26, 1976**

**No. 75-536**

**U.S. Court of Customs and Patent Appeals**

### **Headnotes**

#### **PATENTS**

##### **1. Applications for patent — Continuing (§ 15.3)**

**Patentability — Anticipation — Carrying date back of references (§ 51.203)**

**Patentability — Anticipation — Patents — In general (§ 51.2211)**

**Specification — Sufficiency of disclosure (§ 62.7)**

Claims are entitled to filing dates of parent application under 35 U.S.C. 120 and foreign application that was filed less than one year before parent application under 35 U.S.C. 119 if parent and foreign applications comply with 35 U.S.C. 112, first paragraph, including description requirement, as to claims' subject matter.

##### **2. Foreign patents (§ 38.)**

**Patentability — Anticipation — Carrying date back of references (§ 51.203)**

**Specification — Sufficiency of disclosure (§ 62.7)**

All 35 U.S.C. 119 requires is that foreign application describe and seek protection for broadly same invention as described in U.S. application claiming its benefit.

**3. Court of Customs and Patent Appeals — Issues determined — In general (§ 28.201)**

**Court of Customs and Patent Appeals — Issues determined — Ex parte patent cases (§ 28.203)**

Court of Customs and Patent Appeals, in interests of judicial economy, declines entreaty to determine whether decision's broad rule is still valid, since stated issue is dispositive regardless of decision's validity in its own factual setting; court need not separately decide sufficiency of parent U.S. application of applicants who must have benefit of their foreign application, which contains disclosure regarding limitations that is virtually identical to parent application's, to antedate reference patent.

**4. Specification — Sufficiency of disclosure (§ 62.7)**

Description requirement's function is to ensure that inventor possessed, as of filing date of application relied on, specific subject matter later claimed by him, but how specification accomplishes this is not material; application need not describe claim limitations exactly, but only so clearly that persons of ordinary skill in art will recognize from disclosure that applicants invented processes including those limitations.

**5. Amendments to patent application — In general (§ 13.1)**

**Specification — Sufficiency of disclosure (§ 62.7)**

Primary consideration, in determining whether application describes claim limitations sufficiently clearly that persons of ordinary skill in art will recognize from disclosure that applicants invented processes including those limitations, is factual and depends on invention's nature and amount of knowledge imparted to those skilled in art by disclosure; broadly articulated rules are particularly inappropriate in this area; mere comparison of ranges is not enough, nor are mechanical rules substitute for analysis of each case on its facts to determine whether application conveys to those skilled in art information that applicants invented claims' subject matter; court must decide whether invention applicants seek to protect by their claims is part of invention they described as theirs in specification; fact that what applicants claim as patentable to them is less than what they describe as their invention is not conclusive if their specification also reasonably describes what they do claim; form would otherwise triumph over substance, substantially eliminating applicant's right to retreat to otherwise patentable species merely because he erroneously thought he was first with genus when he filed; patent law

provides for amending claims as well as specification during prosecution, so that 35 U.S.C. 112, second paragraph, "particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention" does not prohibit applicant from changing what he regards as invention, or subject matter on which he seeks patent protection, during application's pendency.

**6. Patentability — Anticipation — Carrying date back of references (§ 51.203)**

**Pleading and practice in Patent Office — Rejections (§ 54.7)**

**Specification — Sufficiency of disclosure (§ 62.7)**

As in cases involving section 112 enablement requirement, Patent and Trademark Office has initial burden of presenting evidence or reasons why persons skilled in art would not recognize in disclosure description of invention defined by claims; pointing to fact that claim reads on embodiments outside description's scope satisfies burden, so that applicants whose claim recites solids content range of "at least 35%" and whose foreign application described 25-60% range have burden of showing that 60% upper limit of solids content described is inherent in claim's limitation "at least 35%"; it is immaterial in ex parte prosecution whether same or similar claims were allowed to others.

**7. Interference — Interference in fact (§ 41.40)**

**Specification — Claims as disclosure (§ 62.3)**

**Specification — Sufficiency of disclosure (§ 62.7)**

Originally filed claim in appealed application is its own written description; disclosure of patent issued after applicants' foreign application is not evidence of what those skilled in art considered conventional at time foreign application was filed for Section 112 purposes; fact that claim's limitation is not material does not matter when limitation is copied; immateriality excuses only failure to copy patent claim's limitation.

**8. Specification — Sufficiency of disclosure (§ 62.7)**

There is important practical distinction between broad generic chemical compound inventions in which each compound within genus is separate embodiment of invention, and invention in which range of solids content is but one of several process parameters; broader range does not describe narrower range where broad described range pertains to different invention

than narrower and subsumed claimed range.

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**9. Patentability — Anticipation — Carrying date back of reference (§ 51.203)**

**Pleading and practice in Patent Office — Rejections (§ 54.7)**

**Specification — Sufficiency of disclosure (§ 62.7)**

Fact that applicants' foreign application describes invention as employing solids contents within 25-60% range along with specific embodiments of 36% and 50% warrants conclusion, in context of process for making freeze-dried instant coffee from concentrated coffee, that persons skilled in art would consider claimed process employing 35-60% solids content range to be part of invention; Patent and Trademark Office's mere argument of lack of literal support is not enough; In re Lukach, 169 USPQ 795, statement that invention claimed does not have to be described in *ipsis verbis* in order to satisfy 35 U.S.C. 112 description requirement would be empty verbiage if lack of literal support alone were enough to support 35 U.S.C. 112 rejection; burden of showing that claimed invention is not described in specification rests on Patent and Trademark Office in first instance, and it is up to it to give reasons why description not in *ipsis verbis* is insufficient.

**10. Amendments to patent application — New matter (§ 13.5)**

**Pleading and practice in Patent Office — Rejections (§ 54.7)**

**Specification — Sufficiency of disclosure (§ 62.7)**

New matter rejection resting on Patent and Trademark Office's conclusion that application as filed did not describe limitation is tantamount to rejection on 35 U.S.C. 112, first paragraph, description requirement.

**11. Patentability — Anticipation — In general (§ 51.201)**

**Patentability — Invention — In general (§ 51.501)**

**Pleading and practice in Patent Office — Rejections (§ 54.7)**

Disclosure in prior art of any value within claimed range is anticipation of claimed range; fact that rejections are under 35 U.S.C. 103 rather than 102 requires considering whether applicants'

invention and patent's disclosure are directed to different purposes and whether persons of ordinary skill in art would not look to reference patent's grandparent application for solution to problem addressed by applicants.

**12. Patentability — Invention — In general (§ 51.501)**

Applicants may not use rationale, that patent and its grandparent application gave no hint of inventive concept of regulating product bulk density to show unobviousness without antecedent basis for it in their application.

**13. Patentability — Invention — Specific cases — In general (§ 51.5091)**

It would be obvious to reduce size of coffee foam particles by suitable mechanical means to desired end product size, in process for making freeze-dried instant coffee, before, rather than after drying.

**14. Patentability — Invention — In general (§ 51.501)**

Applicants whose claim requires freezing over 7 to 25 minute period and who indicate that this produces coffee "having pleasant dark colour" have not overcome prima facie case of obviousness made out by reference disclosing instantaneous freezing, absent showing that only their claimed freezing time produces coffee of pleasant dark color.

**15. Patentability — Invention — In general (§ 51.501)**

**Pleading and practice in Patent Office — Rejections (§ 54.7)**

**Specification — Sufficiency of disclosure (§ 62.7)**

Fact that persons skilled in art may not know how to ensure claimed final product densities from specification is pertinent only to rejection on 35 U.S.C. 112, first paragraph, enablement requirement, and not to whether limitation distinguishes prior art under Section 103.

**16. Patentability — Anticipation — Patent application (§ 51.219)**

**Specification — In general (§ 62.1)**

Applicants' disclosure may not be used against them as prior art absent admission that matter

disclosed in specification is in prior art.

**17. Claims — Article defined by process of manufacture (§ 20.15)**

**Patentability — Invention — In general (§ 51.501)**

Court of Customs and Patent Appeals does not subscribe to broad proposition that process limitations can never serve to distinguish apparatus claims' subject matter from prior art.

**18. Patentability — Anticipation — Patents — In general (§ 51.2211)**

Prior art patents are to be viewed for what they disclose in their entireties and not merely for their inventive contributions to art.

**19. Claims — Article defined by process of manufacture (§ 20.15)**

**Patentability — Invention — In general (§ 51.501)**

**Pleading and practice in Patent Office — Rejections (§ 54.7)**

Patentability of products defined by product-by-process claims, and not processes for making them, is what must be gauged in light of prior art; fact that some products covered by applicants' product-by-process claims may not be suggested by reference patent's grandparent application that completely discloses other subject matter embraced by applicants' claims is not relevant to patentability, complete disclosure in prior art being epitome of obviousness; fact that applicants do not contend that they could not understand basis for rejection because of Patent and Trademark Office's failure to give clear reasons for its action under 35 U.S.C. 132 and explanations given by examiner and Board of Appeals were legally ample under section warrants conclusion that claims that were allegedly improperly grouped with other claims were subject of proper rejection.

**Particular patents — Drying Method**

Wertheim and Mishkin, Drying Method, rejection of claims 1, 4, 6-16, 21-28, 30-35, and 40-43 affirmed; rejection of claims 2, 17-20, 29, 37, and 38 reversed; appeal dismissed as to claims 3, 5, 36, and 39.

**Case History and Disposition:**

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Appeal from Patent and Trademark Office Board of Appeals.

Application for patent of John H. Wertheim and Abraham R. Mishkin, Serial No. 96,285, filed Dec. 8, 1970, continuation of application, Serial No. 537,679, filed Mar. 28, 1966, claiming benefit of Swiss application filed Apr. 2, 1965. From decision rejecting claims 1, 2, 4, 6-35, 37, 38, and 40-43, applicants appeal. Modified; Baldwin and Miller, Judges, dissenting in part with opinions.

**Attorneys:**

William H. Vogt III, and Watson Leavenworth Kelton & Taggart, both of New York, N.Y. (Paul E. O'Donnell, Jr., New York, N.Y., of counsel) for appellants.

Joseph F. Nakamura (Gerald H. Bjorge, of counsel) for Commissioner of Patents and Trademarks.

**Judge:**

Before Markey, Chief Judge, and Rich, Baldwin, Lane, and Miller, Associate Judges.

**Opinion Text**

**Opinion By:**

Rich, Judge.

This appeal is from the decision of the Patent and Trademark Office (PTO) Board of Appeals affirming the final rejection of claims 1-43, all the claims in application serial No. 96,285, filed December 8, 1970, entitled "Drying Method." <sup>1</sup> The appeal on claims 3, 5, 36, and 39 has been withdrawn, and as to these claims it is, therefore, dismissed. As to the remaining claims, we affirm in part and reverse in part.

***The Invention***

Appellants' invention centers around a process for making freeze-dried instant coffee. Claims 1, 6, 30, and 40 are illustrative:

1. An improved process for minimising loss of volatiles during freeze-drying of coffee extract which comprises obtaining coffee extract, concentrating said extract to a higher solids level of at least 35%, foaming said concentrated extract to a substantial





overrun by injection of a gas into said extract at at least atmospheric pressure to thereby avoid evaporative cooling due to evaporation of water in said extract during said foaming, freezing said foam to below its eutectic point at at least atmospheric pressure while avoiding evaporative cooling, and freeze-drying said extract at below the eutectic temperature of said extract.

6. Process for preparing a powdered coffee extract, which comprises adding sufficient inert gas to a concentrated aqueous extract of roast coffee containing about 25% to 60% by weight of soluble coffee solids to provide a foam having a density between about 0.4 and 0.8 gm/cc, freezing the foamed extract to a solid mass, grinding the frozen foam to a particle size of at least 0.25 mm and freeze drying the ground frozen foam.

30. An apparatus for carrying out the process defined in claim 6 comprising, in combination, means for foaming, a closed chamber capable of being maintained at a temperature which is substantially below the melting temperature of said frozen foam, and, disposed within said chamber, a movable endless belt, means for moving said belt at a low speed, a spreading device for distributing coffee extract foam on said belt and refrigerating means for cooling at least one surface of said belt with a liquid refrigerant.

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40. A dry coffee powder comprising a freeze-dried particulated foamed extract of roast and ground coffee, the foam before freeze drying having a density between about 0.4 and 0.8 gm/cc.

The remaining claims are reproduced in the Appendix hereto. Appellants assert that their invention produces an instant coffee having a bulk density of 0.2-0.3 gm/cc, which corresponds to that of conventional spray-dried instant coffee.<sup>2</sup> They allege they discovered that this desired bulk density results from controlling the solids content of the concentrated extract prior to foaming and the density of the foam generated therefrom within the range of their freeze-drying process claims.

Since the claims are somewhat elliptical in setting out the steps of appellants' process, we shall describe it further. An aqueous extract of coffee is prepared by percolating hot water through roasted and ground coffee beans. The extract is concentrated to have a solids content between 25% and 60% and is then charged with gas to produce a foam having a density between 0.4 and 0.8 gm/cc. The foam is frozen and ground into particles, preferably 0.25 to 2.0 mm in size, which are freeze-dried by conventional techniques.

### ***Prosecution History and Rejections***

The claims which remain on appeal fall into two broad groups: The "interference" claims, 1, 2, 4, 37, and 38; and the "non-interference" claims, 6-35 and 40-43.

As originally filed, the application contained claims 1-5 copied from Pfluger et al. U. S. Patent No. 3,482,990 (Pfluger patent), issued December 9, 1969, on an application filed February 10, 1969. A letter under Rule 205(a), 37 CFR 1.205(a), requesting an interference with the Pfluger patent accompanied the application. By amendment, appellants transferred claims 6-35 from their 1966 application to the instant application. Claims 36-39, added by amendment, are modified versions of the previously copied claims and were presented for the purpose of providing a basis for phantom counts in an interference with the Pfluger patent under Rule 205(a) and Manual of Patent Examining Procedure § 1101.02. They depend from claim 2.

The patents relied on by the examiner are:

*Table set at this point is not available. See table in hard copy or call BNA PLUS at 1-800-452-7773 or 202-452-4323.*

The Pfluger patent issued on a chain of four applications: serial No. 800,353, filed Feb. 10, 1969, which was a continuation of serial No. 520,347, filed Jan. 13, 1966 (Pfluger 1966), which was a continuation in-part of serial No. 309,410, filed Sept. 17, 1963 (Pfluger 1963), which was a continuation-in-part of serial No. 98,007, filed Mar. 24, 1961. The Pfluger patent discloses a process for making freeze-dried instant coffee which has as its goal minimizing the loss from a foamed extract of volatile aromatics which contribute substantially to the natural flavor of coffee and other foods.

De George describes apparatus and methods for freezing liquid, unfoamed coffee extract prior to drying on continuous belts refrigerated by brine tanks contacting the bottom surfaces of the belts. The claims of De George are directed to processes for facilitating the removal of the frozen sheet of coffee extract from the belt before it is freeze dried.

The British patent discloses a rapid freeze-drying process in which the food product is frozen, milled into small particles which are spread from a hopper in single-particle layers onto plates, and freeze-dried in a vacuum chamber. More details of the disclosure are supplied infra.

Carpenter discloses the cooling of a refrigeration belt by spraying cold brine onto the underside of the belt.

The examiner made multiple rejections which were addressed by the board in eight categories, seven of which are before us for review. Category I covers the "interference" claims, which were rejected on the Pfluger patent, claims 1, 2, and 4 under 35 USC 102 and claims 37 and 38 under § 103. The board agreed with the examiner's position that these claims were not entitled to the benefit of appellants' 1965 Swiss priority date because they were not supported by appellant's parent and Swiss applications. The limitations held to be unsupported were "at least 35% [solids content]" in claim 1, "between 35% and 60% soluble solids" in claims 2 and 4, and "pressure of less than 500 microns" and "final product

temperature of less than 110°F." in claim 4. For that reason appellants were held to be junior to the Pfluger patent on the basis of Pfluger's 1966 filing date. In light of appellants' refusal to file a Rule 204(c) <sup>3</sup> affidavit showing a date of invention prior to Pfluger's 1966 filing date, the examiner and the board held the Pfluger patent to be prior art under § 102(e) against claims 1, 2, 4, 37, and 38 and rejected the claims on that basis. <sup>4</sup> The board refused to hold that the claims were supported in the parent and Swiss applications, "for interference purposes," under our decision in *In re Waymouth*, 486 F.2d 1058, 179 USPQ 627 (CCPA 1973), mod. on reh., 489 F.2d 1297, 180 USPQ 453 (CCPA 1974). The board stated that appellants' failure to file a Rule 204(c) affidavit precluded any attempt to get into an interference and that *Waymouth*, which concerned the right to make a claim for interference purposes in the application on appeal, was therefore inapplicable to this case.

Under Category II, the board affirmed the rejection of claims 6-10, 12-15, 17, and 26 under 35 USC 132 for new matter. The board held that these claims, which were added to the instant application by amendment, were not supported in the original disclosure for lack of a description of the claimed size of the ground foam particles, i.e., "at least 0.25 mm."

The Category III rejection was reversed by the board.

In Category IV, claims 6-8, 11-20, and 40-43 were rejected under § 103 on the disclosure of Pfluger 1963 <sup>5</sup> carried forward to the Pfluger patent, in accordance with *In re Lund*, supra. The board found that the foam density range of 0.4-0.8 gm/cc claimed by appellants (and the 0.6-0.8 gm/cc range in claims 19 and 20) was suggested by Pfluger 1963's disclosure of 0.1-0.5 gm/cc foam density and that Pfluger 1963 teaches the use of foaming gases and concentrating the coffee extract prior to foaming. The board found that the final product densities claimed would be inherent "in view of the same foam overrun density disclosed by Pfluger" and that Pfluger's example I, which discloses breaking the frozen foam strands into 3/4" lengths (i.e., "at least 0.25 mm") before drying, would suggest the size of the ground foam particles claimed by appellants.

Category V added De George to the § 103 rejection of claims 9, 10, 30, and 32-35. The board agreed with the examiner that the temperatures, foam thicknesses, and belt lengths and speeds covered by these claims are disclosed in De George, and that it would be obvious to use De George's moving belt apparatus in the Pfluger process.

In Category VI claims 21-23 and 26-29 were rejected under § 103 on Pfluger in view of the British patent, which was relied on for its teaching of the concentration of coffee extract by freezing to a solids content of 27 to 28%. Pfluger was applied to the claims under the rationale employed in Category IV.

Category VII was the rejection of claims 24 and 25 under § 103 on Pfluger, the British patent, and De George, which was relied on to show "the deposition of a coffee extract on a moving belt prior to grinding and freeze drying." The board otherwise relied on the reasoning in Categories V and VI.

Under Category VIII claim 31 was rejected on Pfluger and De George under § 103 for the

reasons of Category V, with reliance on Carpenter to show refrigeration of the belt by spraying refrigerant onto the bottom of the belt instead of using De-George's brine tanks.

## **Opinion**

### **The "Interference" Claims — 1, 2, 4, 37, and 38**

[1] The dispositive issue under this heading is whether appellants' parent and Swiss applications comply with 35 USC 112, first paragraph, including the description requirement, as to the subject matter of

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these claims. If they do, these claims are entitled to the filing dates of the parent application under 35 USC 120, *In re Lukach*, 58 CCPA 1233, 442 F.2d 967, 169 USPQ 795 (1971), and the Swiss application under 35 USC 119, *Kawai v. Metlesics*, 480 F.2d 880, 887-88, 178 USPQ 158, 164 (CCPA 1973). Since the PTO relies only on Pfluger 1966 to provide the effective U.S. filing date of the patent as a reference against these claims under §§ 102(e) and 103, a right of foreign priority in appellants' Swiss application will antedate Pfluger 1966 and remove it as prior art against the claims.

[2] The only defect asserted below in appellant's parent and Swiss application disclosures that covers all these claims is that the applications do not contain written descriptions of the solids content limitations of the concentrated extract prior to foaming, i.e., "at least 35%" (claim 1) and "between 35% and 60%" (claims 2, 4, 37, and 38).<sup>6</sup>

[3] Appellants' parent and Swiss applications contain virtually identical disclosures on this point. Both disclose that the coffee extract initially produced by percolation of water through ground roasted coffee is concentrated prior to foaming by suitable means "until a concentration of 25 to 60% solid matter is reached." Examples in each disclose specific embodiments having solids contents of 36% and 50%.

In our view, it is necessary to decide only whether the Swiss application complies with the description requirement of § 112 with respect to the questioned limitations. There is no question that the *instant* application supports claims 1, 2, and 4, which are original claims in that application. Appellants and the solicitor urge us to decide this case by determining whether the broad rule of *In re Waymouth*, *supra*, is still valid or must be disapproved. In the interest of judicial economy, we decline this entreaty since the issue of whether the Swiss application contains written descriptions of the disputed limitations of claims 1, 2, 4, 37, and 38, being addressed to strict compliance with § 112, first paragraph, is dispositive regardless of the validity of *Waymouth* in its own factual setting. The sufficiency of the parent U. S. application need not be separately decided since appellants must have the benefit of their Swiss application date to antedate the Pfluger patent.

[4] The function of the description requirement is to ensure that the inventor had possession,

as of the filing date of the application relied on, of the specific subject matter later claimed by him; how the specification accomplishes this is not material. In re Smith, 481 F.2d 910, 178 USPQ 620 (CCPA 1973), and cases cited therein. It is not necessary that the application describe the claim limitations exactly, In re Lukach, supra, but only so clearly that persons of ordinary skill in the art will recognize from the disclosure that appellants invented processes including those limitations. In re Smythe, 480 F.2d 1376, 1382, 178 USPQ 279, 284 (CCPA 1973).

[5] The primary consideration is *factual* and depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure. The factual nature of the inquiry was emphasized in In re Ruschig, 54 CCPA 1551, 1558-59, 379 F.2d 990, 995-96, 154 USPQ 118, 123 (1967), which involved the question whether a broad generic disclosure "described" the single chemical compound claimed:

But looking at the problem, as we must, from the standpoint of one with no foreknowledge of the specific compound, it is our considered opinion that the board was correct in saying:

Not having been specifically named or mentioned in any manner, one is left to selection from the myriads of possibilities encompassed by the broad disclosure, with no guide indicating or directing that this particular selection should be made rather than any of the many others which could also be made.

Appellants refer to 35 USC 112 as the presumed basis for this rejection and emphasize language therein about *enabling* one skilled in the art to *make* the invention, arguing therefrom that one skilled in the art would be enabled by the specification to make chlorpropamide. We find the argument unpersuasive for two reasons. First, it presumes some motivation for

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wanting to make the compound in preference to others. While we have no doubt a person so motivated would be enabled by the specification to make it, this is beside the point for the question is not whether he would be so enabled but whether the specification discloses the compound to him, specifically, as something appellants actually invented. We think it does not. Second, we doubt that the rejection is truly based on section 112, at least on the parts relied on by appellants. If based on section 112, it is on the requirement thereof that "The specification shall contain a written description *of the invention* \* \* \*." [Emphasis ours.] We have a specification which describes appellants' invention. The issue here is in no wise a question of its compliance with section 112, it is a question of *fact*: *Is the compound of claim 13 described therein?* Does the specification convey clearly to those skilled in the art, to whom it is addressed, in any way, the information that appellants invented that specific compound?

Broadly articulated rules are particularly inappropriate in this area. See, e.g., In re Smith, 59 CCPA 1025, 1033, 458 F.2d 1389, 1394, 173 USPQ 679, 683 (1972), in which this court felt

obliged to overrule a supposed "rule" of *In re Risse*, 54 CCPA 1495, 1500-01, 378 F.2d 948, 952-53, 154 USPQ 1, 5 (1967). Mere comparison of ranges is not enough, nor are mechanical rules a substitute for an analysis of each case on its facts to determine whether an application conveys to those skilled in the art the information that the applicant invented the subject matter of the claims. In other words, we must decide whether the invention appellants seek to protect by their claims is part of the invention that appellants have described *as theirs* in the specification. That what appellants claim as patentable to them is *less* than what they describe as their invention is not conclusive if their specification also reasonably describes that which they do claim. Inventions are constantly made which turn out not to be patentable, and applicants frequently discover during the course of prosecution that only a part of what they invented and originally claimed is patentable. As we said in a different context in *In re Saunders*, 58 CCPA 1316, 1327, 444 F.2d 599, 607, 170 USPQ 213, 220 (1971):

To rule otherwise would let form triumph over substance, substantially eliminating the right of an applicant to retreat to an otherwise patentable species merely because he erroneously thought he was first with the genus when he filed. Cf. *In re Ruff*, 45 CCPA 1037, 1049, 256 F.2d 590, 597, 118 USPQ 340, 347 (1958). Since the patent law provides for the amendment during prosecution of *claims*, as well as the specification supporting claims, 35 USC 132, it is clear that the reference to "particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention" in the second paragraph of 35 USC 112 does not prohibit the applicant from changing what he "regards as his invention" (i.e., the subject matter on which he seeks patent protection) during the pendency of his application. Cf. *In re Brower*, 58 CCPA 724, [728] 433 F.2d 813, 817, 167 USPQ 684, 687 (1970) (fact that claims in continuation application were directed to subject matter which appellants had not regarded as part of their invention when the parent application was filed held not to prevent the continuation application from receiving benefit of parent's date).

[6] Claims 1 and 4 present little difficulty. Claim 1 recites a solids content range of "at least 35%," which reads literally on embodiments employing solids contents outside the 25-60% range described in the Swiss application. As in cases involving the enablement requirement of § 112, e.g., *In re Armbruster*, 512 F.2d 676, 185 USPQ 152 (CCPA 1975), we are of the opinion that the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims. By pointing to the fact that claim 1 reads on embodiments outside the scope of the description, the PTO has satisfied its burden. Appellants thus have the burden of showing that the upper limit of solids content described, i.e., 60%, is inherent in "at least 35%," as that limitation appears in claim 1. Appellants have adduced no evidence to carry this burden as to claim 1, and they argue only that since the Pfluger patent contains claim 1 supported by Pfluger's disclosure with a stated upper limit of 60%, like appellants' Swiss disclosure, refusal to grant appellants claim 1 amounts to an illegal reexamination of claim 1 in Pfluger. However, as we have often repeated, as recently as *In re Giolito*, 530 F.2d 397, 188 USPQ 645 (CCPA 1976), it is immaterial in *ex parte* prosecution whether the same or similar claims have been allowed to others.

[7] Claim 4 contains the additional limitations, relating to the "final product temperature" and the pressure at which the frozen foam is vacuum freeze-dried, of "less

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than 100°F. and "less than 500 microns." "Final product temperature," it appears, refers to the temperature at which so-called bound water is driven off from the product by heating after the vacuum drying phase has ended. We find no description of final product temperature in appellants' Swiss application. It is not disputed that appellants do not expressly disclose final product temperatures or this secondary drying step. They again appeal, however, to the Pfluger patent disclosure and to an amendment entered in the application on appeal (not objected to as new matter by the examiner) to show that final product temperatures are conventional in the art and need not be expressly disclosed. The amendment is clearly irrelevant since claim 4, an originally filed claim, is its own written description in the appealed application. In re Gardner, 475 F.2d 1389, 177 USPQ 396, rehearing denied, 480 F.2d 879, 178 USPQ 149 (CCPA 1973). The issue is whether the Swiss application describes the claimed final product temperature, not whether the instant application does so. The Pfluger patent disclosure is also unavailable to appellants. The Swiss application was filed before Pfluger issued, which means that for the purposes of § 112 the Pfluger disclosure is not evidence of what those skilled in the art considered conventional at the time the Swiss application was filed. In re Glass, 492 F.2d 1228, 181 USPQ 31 (CCPA 1974).<sup>7</sup>

Claims 1 and 4, therefore, are not entitled to the benefit of the filing date of appellants' Swiss application.

[8] Claims 2, 37, and 38, which claim a solids content range of "between 35% and 60%," present a different question. They clearly claim a range *within* the described broad range of 25% to 60% solids; the question is whether, *on the facts*, the PTO has presented sufficient reason to doubt that the broader described range also describes the somewhat narrower claimed range. We note that there is no evidence, and the PTO does not contend otherwise, that there is in fact any distinction, in terms of the operability of appellants' process or of the achieving of any desired result, between the claimed lower limit of solids content and that disclosed in the Swiss application. We see an important practical distinction between broad generic *chemical compound* inventions, for example, as in In re Ruschig, *supra*, in which each compound within the genus is a separate embodiment of the invention, and inventions like that at bar, in which the range of solids content is but one of several process parameters. What those skilled in the art would expect from using 34% solids content in the concentrated extract prior to foaming instead of 35% is a different matter from what those skilled in the art would expect from the next adjacent homolog of a compound whose properties are disclosed in the specification. We wish to make it clear that we are not creating a rule applicable to all description requirement cases involving ranges. Where it is clear, for instance, that the broad described range pertains to a different invention than the narrower (and subsumed) claimed range, then the broader range does not describe the narrower range. In re Baird, 52 CCPA 1747, 348 F.2d 974, 146 USPQ 579 (1965);

In re Draeger, 32 CCPA 1217, 150 F.2d 572, 66 USPQ 247 (1945).

[9] In the context of *this* invention, in light of the description of the invention as employing solids contents within the range of 25-60% along with specific embodiments of 36% and 50%, we are of the opinion that, as a factual matter, persons skilled in the art would consider processes employing a 35-60% solids content range to be part of appellants' invention and would be led by the Swiss disclosure so to conclude. Cf. In re Ruschig, *supra*. The PTO has done nothing more than to argue lack of literal support, which is not enough. If lack of literal support alone were enough to support a rejection under § 112, then the statement of In re Lukach, *supra*, 58 CCPA at 1235, 442 F.2d at 969, 169 USPQ at 796, that "the invention claimed does not have to be described in *ipsis verbis* in order to satisfy the description requirement of § 112," is empty verbiage. The burden of showing that the claimed invention is not described in the specification rests on the PTO in the first instance, and it is up to the PTO to give reasons why a description not in *ipsis verbis* is insufficient.

We conclude, therefore, that claims 2, 37, and 38 are entitled to the benefit of the filing date of appellants' Swiss application.

Since the Pfluger patent is not available as prior art as of its 1966 date under §§ 102(e) and 103 against claims 2, 37, and 38, the rejection of those claims is reversed. The rejection of claims 1 and 4 is affirmed. Appellants filed no affidavit under Rule 204(c) showing a date of invention for claims 1 and 4 prior

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to Pfluger's 1966 filing date, In re Gemassmer, 51 CCPA 726, 319 F.2d 539, 138 USPQ 229 (1963), and have not antedated Pfluger as to those claims under 35 USC 119 and 120.

### ***The New Matter Rejection***

[10] The issue to be decided here is whether the limitation appearing in claim 6, carried forward into the other claims affected by this rejection, that the frozen foam be ground "to a particle size of at least 0.25 mm" before it is dried, was added to the instant application in violation of 35 USC 132. This new matter rejection rests on a finding by the PTO that the application as filed did not describe this limitation. Thus, the converse of what we said in In re Bowen, 492 F.2d 859, 864, 181 USPQ 48, 52 (CCPA 1974), is true in this case, namely, that this new matter rejection is tantamount to a rejection of the claims on the description requirement of 35 USC 112, first paragraph. The solicitor agrees with this.

We conclude that the originally filed specification clearly conveys to those of ordinary skill in the art that appellants invented processes in which the frozen foam is ground to a particle size of "at least 0.25 mm," and not, as the PTO asserts, only processes in which the particle sizes are no larger than 2 mm. See In re Smythe, *supra*.

The specification states, *inter alia* (emphasis ours):



At the end of the [cooling] belt the extract is removed as a continuous rigid sheet which *may* then be broken up into fragments suitable for grinding. These fragments *may, for example,* be ground to a particle size which is *preferably* within the range 0.25 to 2.0 mm.

In a modification of the process, the frozen extract may be freeze-dried in the form of *plates or lumps* which are *subsequently* ground to the desired particle size.

The examples speak of drying frozen ground particles of sizes between 0.1 and 2 mm. While the specification indicates that the 0.25 to 2.0 mm range is preferred, we think it clearly indicates that, as an alternative embodiment of appellants' invention, the foam may be dried in lumps or plates of undisclosed size, which are reduced to the obviously smaller preferred particle size by grinding only *after* being dried. The solicitor argues that the claimed "range" has no upper limit, wherefore it is not disclosed. The clear implication of this disclosed modification is that appellants' specification does describe as their invention processes in which particle size is "at least 0.25 mm," without upper limit, as delineated by the rejected claims. The rejection of claims 6-10, 12-15, 17, and 26 under 35 USC 132 is reversed.

### ***The "Non-Interference" Claims — 6-35 and 40-43***

In the Examiner's Answer, appellants were granted the benefit of the filing date of their Swiss application for claims 16-25, 27-35, and 40-43. The examiner stated: "Claims 6-15 and 26, except for new matter, would otherwise be supported in the Swiss application." Our reversal of the new matter rejection eliminates the basis for the examiner's refusal to give claims 6-15 and 26 the benefit of appellants' Swiss filing date. Appellants' parent and Swiss applications contain the same disclosures concerning particle size as does the application on appeal, and we shall treat all the claims under this heading as entitled to the right of foreign priority claimed by appellants.

Our analysis of these claims will be broken down by the type of claim involved, i.e., process, apparatus, and product, and not as the board addressed them. In each discussion we will apply as prior art under § 102(e) only those portions of the Pfluger patent disclosure that were carried forward from the Pfluger 1963 application (Pfluger 1963) through the two subsequent applications into the patent, as did the board. In *re Lund*, *supra*.

#### ***A. Process Claims 6-14 and 16-29***

There are four independent process claims: claims 6, from which claims 7-14, 16, and 17 depend; claim 18; claim 19, from which claim 20 depends; and claim 21, from which claims 22-29 depend.

Pfluger 1963 contains the following disclosure, which, in substance, is carried forward into the patent:

This invention is founded on the discovery that an aqueous aromatic liquid containing solids in suspension and solution may be dried without undergoing loss of

aromatic volatiles by a process which comprises foaming the aqueous liquid to a substantial overrun while avoiding evaporation of said aqueous liquid, freezing said foam to below its eutectic point while avoiding evaporation of the aqueous liquid, subliming said aqueous liquid from the frozen foam to reduce the moisture of the foam to at least 10-20%, and further drying the foam to a stable moisture content.

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In many applications such foaming can be considerably increased by concentrating the solution or suspension to a relatively high solids content prior to incorporation of air or other gas such as nitrogen therein by first whipping and then freezing the foam, preferably by conductive freezing. During the foaming step, it is essential in order to prevent loss of volatiles to avoid any evaporative cooling of the material, i.e., evaporation of water during the foaming step. Also, during the freezing step evaporative cooling should be avoided. Other ways for creating a frozen foam without undergoing evaporative cooling involve the overt introduction to a solution or suspension of dry ice, i.e., solid carbon dioxide in a suitably ground or particulate form, whereby carbon dioxide gas is liberated upon subliming of the "dry ice" to cause foaming of the solution or suspension to occur. Similarly, refrigerated air or nitrogen can be introduced to the solution or suspension to cause freezing thereof incident to foaming the material. The foam preferably has a high overrun whereby the density of the solution or suspension is changed from above 1.0 gm./cc. to between 0.1-0.5 gms/cc.

Example I, the sole disclosed embodiment in which the foam density is given, shows foaming the extract to a density of 0.22 gm/cc.

Claims 19 and 20 recite a foam density of "between about 0.6 and about 0.8 gm/cc," outside the range disclosed by Pfluger 1963. The examiner's position was that Pfluger's disclosure of 0.5 gm/cc as an upper density limit suggests "about 0.6 gm/cc" as the lower limit in the processes of claims 19 and 20 "in the absence of a critical difference between them." We see no such suggestion. By preferring a high foam overrun, i.e., lower rather than higher foam densities, Pfluger 1963 teaches away from employing higher foam densities than its disclosed upper limit of 0.5 gm/cc. Appellants' "about 0.6 gm/cc" lower limit is sufficiently precise to describe foam densities above 0.5 gm/cc and thus outside the range of foam densities that persons of ordinary skill in the art would have been motivated to use by Pfluger 1963's disclosure of a preference for high overrun foams no denser than 0.5 gm/cc. The examiner's comment about the lack of a showing of a critical difference is based on his failure to appreciate that Pfluger 1963 teaches away from increasing foam density. The rejection of claims 19 and 20 under § 103 is reversed.

[11] Claims 6-14, 16, 17, and 21-29 recite foam density ranges of "between about 0.4 and 0.8 gm/cc" and solids contents in the range of "about 25% to 60%." Claims 6-10, 12-14, 17, and 26 recite particle sizes of "at least 0.25 mm," claims 16 and 27 say "about 0.25 to 2 mm," claims 11 and 28 recite particle sizes "approximately equal to that of roast and ground coffee," and claims

21-25 do not mention particle size. Pfluger 1963's disclosed foam density range of 0.1-0.5 gm/cc covers values within the scope of all the above-listed claims; the solids contents disclosed in Pfluger 1963 Examples I (27%) and V (30%) are within the claimed ranges of 25-60%. Pfluger 1963 clearly teaches a process for making instant coffee comprising the steps of preparing and concentrating aqueous coffee extract, foaming the extract then freezing the foam, and drying the frozen foam, in that order. Pfluger 1963 teaches fragmenting the frozen foam into 3/4-inch pieces before drying; 3/4 inch is, of course, "at least 0.25 mm." Of course, the disclosure in the prior art of any value within a claimed range is an anticipation of the claimed range. We appreciate the arguments made in *In re Malagari*, 499 F.2d 1297, 182 USPQ 549 (CCPA 1974), and the discussion in *In re Orfeo*, 58 CCPA 1123, 440 F.2d 439, 169 USPQ 487 (1971), to the effect that ranges which overlap or lie inside ranges disclosed by the prior art may be patentable if the applicant can show criticality in the claimed range by evidence of unexpected results. The rejections here are under § 103, not § 102, which requires us to consider appellants' argument that their invention and Pfluger's disclosure are directed to different purposes and that persons of ordinary skill in the art would not look to Pfluger 1963 for a solution to the problem addressed by appellants. See *In re Orfeo*, supra.

[12] Appellants' contentions were thus stated in their main brief:

The Board erred at the threshold in failing to appreciate that neither the Pfluger patent nor the 1963 Pfluger application gives any inkling or hint of the inventive concept underlying the rejected claims. \* \* \* The Pfluger disclosures make no mention of product bulk density and contain no suggestion of altering or regulating that density in any manner. Neither does the reference suggest appellants' step of grinding the foam before freeze drying.

One of ordinary skill in the art reading the 1963 Pfluger disclosure would have no

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inkling of the problem addressed and solved by appellants; and one looking for ways to meet that problem would have no occasion to consider Pfluger or his expedients.

Without an antecedent basis for it in their application, appellants may not use this rationale to show unobviousness. *In re Davies*, 475 F.2d 667, 177 USPQ 381 (CCPA 1973). While appellants do disclose what the bulk density of their product "usually" is, we find no suggestion in appellants' application that their invention is addressed to the regulation of the bulk density of the product, and the claims make no express reference to such regulation. The only references in appellants' disclosure to this alleged problem and its solution which are apparent to us are (emphasis ours):

After freeze-drying, the coffee extract is obtained in the form of a powder the density of which is *usually* 0.2 to 0.3 gm/cc.

Drying of the concentrated extract should *desirably* be carried out *under*

*controlled conditions* such that the finished product possesses an appropriate *density* and colour.\*\*\*

\*\*\* The conditions of freezing, notably belt speed, freezing temperature, thickness of foam layer as well as the *density of the foam*, are factors which have an important *influence* on the *colour* of the finished product and should therefore be carefully controlled.

The inadequacy of this disclosure is evident. There is no mention of *regulating* the final product density or of controlling solids content. We therefore see no basis for depreciating Pfluger as evidence of the scope and content of the prior art, as well as of the level of ordinary skill in this art, as appellants would have us do. Nor is there any factual basis for concluding that the ranges claimed by appellants are critical in themselves to their alleged inventive contribution.

[13] We find no error in the rejection under § 103 of claims 6-14, 16, and 21-28, which recite no final product density. The only difference between claims 6, 12-14, and 16 and the Pfluger 1963 disclosure upon which appellants rely to show the unobviousness of the subject matter of the claims (and which does not relate to solids content or foam density) is the step of "grinding the frozen foam to a particle size of at least 0.25 mm" *prior* to freeze-drying. <sup>8</sup> Pfluger 1963, appellants assert, "fragments" the frozen foam prior to drying and "grinds" the foam only after it has been dried. As indicated above, the size of the fragments of frozen foam disclosed by Pfluger 1963 is "at least 0.25 mm." We do not think this difference shows the subject matter to be unobvious. Pfluger 1963 implies that the sizes of foam particles before and after drying are comparable; it would have been obvious to reduce the size of the foam particles by suitable mechanical means, whether it be called fragmenting or grinding, to the desired end product size before rather than after drying. Claim 11 differs only in its recitation of final product particle size, which Pfluger 1963 shows is an obvious matter of choice for those of ordinary skill in the art, who know how large ground roasted coffee bean particles are. The commercial motivation for making the particles this size is obvious. Appellants have not argued the patentability separately from claim 6 of claims 9 and 10, which add temperature and foam thickness limitations suggested by Pfluger and De George, as discussed *infra* in considering claims 24 and 25.

[14] Claim 8 likewise recites no final product density, but it requires that the freezing of the foam take place over a period of 7 to 25 minutes, which, appellants' application indicates, produces instant coffee "having a pleasant dark colour." Pfluger 1963 discloses freezing in liquid nitrogen or liquid air, which would be instantaneous, or rapid freezing on a belt, and states further, "The foam may be frozen at a high or a more gradual rate *without any apparent difference* in the utility thereof insofar as freeze drying is concerned \*\*\*." (Emphasis ours.) Appellants have not shown that only their claimed freezing time produces coffee with a pleasant dark color. Thus, they have not overcome the *prima facie* case of obviousness made out by Pfluger 1963.

In light of appellants' concession in the amendment in which they added claims 37-39 that

freeze concentration was known in the art, the rejection of claims 21-23, and 26-28 under Category VI, *supra*, becomes little more than a rejection on Pfluger 1963 alone. With the exception of freeze concentration, which is disclosed by the British patent, every element of claim 21 is disclosed by Pfluger 1963, as indicated *supra*. Appellants advance no arguments for the patentability of claim 21 different from those

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we have already rejected for claim 6. Claim 22 adds only a recitation of the inert gases used in the foaming step, which were known in the prior art. Claims 26-28 recite the particle sizes of claims 6, 16, and 11, respectively; these particle sizes are not sufficient to show unobviousness for the reasons given *supra*. Claim 23, which was also rejected under Category VI, recites the freezing time of claim 8. It is unpatentable for the same reasons given for claim 8, *supra*.

Claims 24 and 25, to which Pfluger 1963, De George, and the British patent were applied under § 103, call for the temperature and foam limitations already discussed under claims 9 and 10, *supra*. Temperature and foam thickness within the claimed ranges are disclosed by Pfluger 1963 in Example VI (freezing foam at — 30°F. on a belt and subsequently loading foam onto trays to a 1-inch (approx. 25mm) depth for vacuum drying). Appellants do not allege that the ranges of claims 24 and 25 are critical.

[15] Claims 17, 18, and 29, on the other hand, recite the bulk density of the final product made by each process in positive terms. The board dismissed these final product density limitations as being merely recitations of the inherent result of observing the foam density and solids content ranges set forth in these claims. Although we found above that appellants' specification as filed does not disclose regulating product density by controlling the foam density and solids content in the process and that claims which failed to recite controlled product density could not rely on this feature to distinguish over the prior art under § 103, these claims do require such regulation or control, by implication through their express recitation of the density of the final product to be obtained from the processes they delimit. That persons skilled in the art may not know how to ensure the claimed final product densities from the specification is pertinent only to a rejection on the enablement requirement of § 112, first paragraph, which is not before us. The only question here is whether the subject matter of claims 17, 18, and 29, the scope of which is unquestionably clear, is obvious under § 103.

[16] Pfluger 1963 discloses no final product densities and contains no teaching on how to achieve any particular final product density from practicing its process. The inherency of final product density adverted to by the board can be gleaned only from appellants' disclosure, if anywhere, which may not be used against them as prior art absent some admission that matter disclosed in the specification is in the prior art. *In re Kuehl*, 475 F.2d 658, 177 USPQ 250 (CCPA 1973); cf. *In re Nomiya*, 509 F.2d 566, 184 USPQ 607 (CCPA 1975). In the absence of disclosure of final product densities or how to achieve any desired density in the prior art applied by the PTO to claims 17, 18, and 29, we cannot say that the subject matter of these claims would

have been obvious to persons of ordinary skill in the art.

The rejection of process claims 6-14, 16, and 21-28 is affirmed; the rejection of claims 17-20, and 29 is reversed.

### **B. Apparatus Claims 30-35**

[17] The preamble of independent claim 30, carried forward into claims 31-35, recites that the apparatus is "for carrying out the process in claim 6." Appellants contend that this preamble gives "life and meaning" to the claims, serving to define the interrelationship of the mechanical elements recited in the body of the claims. This argument appears to be based on *Kropa v. Robie*, 38 CCPA 858, 187 F.2d 150, 88 USPQ 478 (1951), the classic case in this court on the construction of claim preambles. In *Kropa* the court surveyed prior cases and said 38 CCPA at 861, 187 F.2d at 152, 88 USPQ at 480-81:

[I]t appears that the preamble has been denied the effect of a limitation where the claim or count was drawn to a structure and the portion of the claim following the preamble was a self-contained description of the structure not depending for completeness upon the introductory clause \* \* \*. In those cases, the claim or count apart from the introductory clause completely defined the subject matter, and the preamble merely stated a purpose or intended use of that subject matter.

While we do not subscribe to the broad proposition that process limitations can never serve to distinguish the subject matter of apparatus claims from the prior art, we fail to see how the general process parameters of claim 6 require an arrangement of the apparatus means recited in claims 30-35 more specific than that set forth in the body of each claim. In no claim is the preamble relied on to provide an antecedent basis for terms in the body. See *In re Higbee*, 527 F.2d 1405, 188 USPQ 488 (CCPA 1976). The context of each invention is clear without reference to claim 6, unlike the situation in *Kropa*, supra, in which the preamble "An abrasive article" was the only portion of the claim defining the relationship of the components recited in the body of the claim; the court said, "The term calls forth a distinct relationship between

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the proportions of grain and resin comprising the article." 38 CCPA at 862, 187 F.2d at 152, 88 USPQ at 481.

[18] Appellants do not argue the patentability of claims 32-35 separately from claim 30 and concede that Carpenter discloses the feature added in claim 31. We find that the teachings of Pfluger and De George (and Carpenter on claim 31) show that the subject matter of claims 30-35 would have been obvious to persons of ordinary skill in the art. These references are to be viewed for what they disclose in their entireties and not merely for their inventive contributions to the art. *In re Ogiue*, 517 F.2d 1382, 1387, 186 USPQ 227, 232 (CCPA 1975).

Pfluger 1963, in a portion carried forward to the patent, discloses the following:

Advantageously, in following the teachings of the present process either in a vacuum-freeze drying application or in an atmospheric-freeze drying application, the frozen foamy mass may be arranged for either batch or continuous processing in any one of a variety of conventional plant handling applications. Thus, the foamy mass can be readily transferred from one food handling station to another, deposited in trays or continuous belts, superimposed on one another or otherwise conventionally located in the vicinity of the freeze drying influences. In the case of a typical freeze drying operation the foams may be frozen and deposited onto trays stacked one above the other on a suitable heat transfer surface in a vacuum chamber. In the case of an atmospheric freeze drying application the foams can be stacked one upon the other upon a foraminous drying member permitting the circulation of the drying medium, e.g. dry air, helium or nitrogen. Throughout all of such freeze drying applications it is imperative that the temperature of the foamy mass be maintained below the eutectic point of the material while drying to assure that the foam stays in a substantially solid or frozen state as distinguished from a melted or semi-liquid state, dehydration of the mass being achieved by a process of sublimation as distinguished from one of evaporation. Such conditions should be followed at least until the moisture content of the foamy mass has been substantially reduced to a point where it has lost at least a majority of its moisture and preferably is superficially dry to the touch, i.e. in the neighborhood of 10-20% moisture by weight.

Example VI of Pfluger 1963, which is carried forward as Example III of the Pfluger patent, shows heat controlling the vacuum chamber to assure a product temperature below  $-10^{\circ}\text{F}$ . (De George teaches that the melting point of a 28% solids content extract is about  $27^{\circ}\text{F}$ ., whereas the eutectic temperature is constant regardless of concentration at about  $-13.5^{\circ}\text{F}$ .) De George discloses the use of endless belts, low speeds, and refrigerating means, and appellants, while arguing that De George treats the handling of solid slabs of frozen extract on refrigeration belts and not frozen foamed extracts, do not and cannot deny that De George discloses apparatus that persons of ordinary skill in the art would have deemed *suitable* for handling foams in the manner shown by Pfluger. Appellants also contend that neither reference discloses the "spreading device" recited in the claims, Pfluger 1963 showing only the application of  $\frac{1}{8}$  diameter ribbons of foam through a nozzle to stationary freeze drying trays. The reference in the portion of Pfluger 1963 quoted supra to the deposition of the foam on the belts is ample suggestion, in our opinion, that some means must be employed to apply the foamy mass to the continuous belts. The term "spreading device" is not defined in any special way by appellants and is broad enough to be the means for applying the foam to the belt suggested by Pfluger. The rejection of claims 30-35 is affirmed.

### **C. Product Claims 15 and 40-43**

[19] These claims are cast in product-by-process form. Although appellants argue, successfully we have found, that the Pfluger 1963 disclosure does not suggest the control of bulk density afforded by appellants' process, the patentability of the *products* defined by the claims, rather than the processes for making them, is what we must gauge in light of the prior art. See In

re Bridgeford, 53 CCPA 1182, 357 F.2d 679, 149 USPQ 55 (1966). Each of these claims defines a freeze-dried instant coffee product made by processes which, appellants have contended with respect to their process claims, produce, by virtue of the foam density and solids content ranges taught by appellants, products having a bulk density comparable to spray-dried instant coffee, i.e., 0.2-0.3 gm/cc as indicated in appellants' specification. The solids content and foam density ranges disclosed by Pfluger 1963 overlap those of appellants, and, it appears, the Pfluger process using solids contents and foam densities overlapping those of appellants will produce instant coffee which is indistinguishable from appellants' products. There is no evidence showing that Pfluger's product prepared, for example, using an extract of 30% solids con

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tent foamed to a density of 0.5 gm/cc differs from appellants' claimed products in any way, certainly not in any unobvious way. See In re Avery, 518 F.2d 1228, 1233-34, 186 USPQ 161, 165-66 (CCPA 1975). That *some* of the products *covered* by appellants' claims may not be disclosed or suggested by Pfluger 1963 is not relevant to patentability, since the claims embrace other subject matter completely disclosed by Pfluger 1963, complete disclosure in the prior art being the epitome of obviousness. In re Pearson, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974). The rejection of these product claims under § 103 on Pfluger<sup>9</sup> is affirmed.

## **Conclusion**

The appeal is dismissed as to withdrawn claims 3, 5, 36, and 39. The decision of the board is affirmed as to claims 1, 4, 6-16, 21-28, 30-35, and 40-43, and is reversed as to claims 2, 17-20, 29, 37, and 38.

## **APPENDIX**

2. The process of claim 1 wherein the extract is concentrated to between 35% and 60% soluble solids prior to the foaming step.
3. The process of claim 2 wherein the concentrated extract is foamed to an overrun density of between 0.1 to 0.7 gm/cc.
4. The process of claim 2 wherein the frozen foam is vacuum freeze-dried at a pressure of less than 500 microns and a final product temperature of less than 110°F.
5. The process of claim 3 wherein the frozen foam is vacuum freeze-dried at a pressure of less than 500 microns and a final product temperature of less than 110°C.
7. A process according to claim 6 in which said inert gas is at least one of the following gases, namely carbon dioxide, nitrous oxide and nitrogen
8. A process according to claim 6 in which the foam is frozen during 7 to 25 minutes.
9. A process according to claim 6 in which the foam is frozen on a moving belt which is



cooled to a temperature between  $-12$  and  $-70^{\circ}\text{C}$ .

10. A process according to claim 6 wherein the foam is spread on the belt at a layer thickness of 10 to 40 mm.

11. A process according to claim 6 in which the frozen foam is ground, before freeze-drying, to a particle size approximately equal to that of roast and ground coffee.

12. A process according to claim 6 in which an aromatic condensate obtained by stripping roast and ground coffee is added to said concentrated extract before it is transformed into a foam.

13. A process according to claim 6 in which, after freeze-drying, the powdered coffee extract is aromatised by incorporation therein of 0.1 to 0.5% by weight of an aromatic condensate obtained by stripping of roast and ground coffee.

14. A process according to claim 13 in which said condensate is incorporated in said powdered extract in admixture with an oily carrier.

15. The coffee extract obtained by the process defined in claim 6.

16. Process according to claim 6 in which the frozen foam is ground to a particle size of about 0.25 to 2.0 mm.

17. Process according to claim 6 in which the freeze dried extract has a density of about 0.2 to 0.3 gm/cc.

18. Process for preparing a soluble coffee extract, which comprises adding inert gas to a concentrated aqueous extract of roast coffee having a solids content of about 25% to about 60% to provide a foam, freezing the foam to a solid mass, reducing the frozen foam to particles having a size of about 0.25 to 2.0 mm and freeze drying the frozen particles, the amount of inert gas added to the aqueous extract being sufficient to provide a freeze dried extract having a density between about 0.2 and 0.3 gm/cc.

19. Process for preparing a powdered coffee extract which comprises adding sufficient inert gas to a concentrated aqueous extract of roast coffee to provide a foam having a density between about 0.6 and about 0.8 gm/cc, freezing the foamed extract to a solid mass, grinding the frozen foam to an average particle size of 0.1 to 0.5 mm, freeze drying the ground particles to provide a finely powdered coffee extract, and agglomerating the finely powdered coffee extract.

20. Process according to claim 19, in which the powdered extract is agglomerated to provide an agglomerate having a density of about 0.2 to 0.3 gm/cc.

21. Process for preparing a powdered coffee extract which comprises increasing the soluble coffee solids content of an aqueous extract of roast ground coffee to about 25% — 60% by freeze concentration, separating the concentrated extract from ice crystals, adding an inert gas to the concentrated aqueous extract to provide a foam having a density between about 0.4 and 0.8

gm/cc, freezing the foam to a solid mass and freeze drying the frozen foam.

22. Process according to claim 21 in which the inert gas is selected from the group consisting of carbon dioxide, nitrous oxide and nitrogen.

23. Process according to claim 21 in which the foam is frozen during 7 to 25 minutes.

24. Process according to claim 21 in which the foam is frozen on a moving belt which is cooled to a temperature between  $-12$  and  $-70^{\circ}\text{C}$ .

25. Process according to claim 24 wherein the foam is spread on the belt at a layer thickness of 10 to 40 mm.

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26. Process according to claim 21 in which the frozen foam is ground before freeze drying to a particle size of at least 0.25 mm.

27. Process according to claim 26 in which the frozen foam is ground to a particle size of about 0.25 to 2 mm.

28. Process according to claim 21 in which the frozen foam is ground before freeze drying to a particle size approximately equal to that of roast and ground coffee.

29. Process according to claim 21 in which the freeze dried extract has a density of about 0.2 - 0.3 gm/cc.

31. An apparatus according to claim 30 in which the means for cooling the belt includes a plurality of sprinklers disposed to spray the refrigerant onto the underside of the belt.

32. An apparatus according to claim 30 in which the belt comprises two sections each provided with separate cooling means, the first of said sections being cooled to a temperature of  $-12$  to  $-29^{\circ}\text{C}$  and the second section to  $-40$  to  $-70^{\circ}\text{C}$ .

33. An apparatus according to claim 30 also comprising means for fragmenting and milling the frozen foam.

34. An apparatus according to claim 30 in which the length of said belt is 15 to 25 metres and the driving means is adapted to move said belt at a linear speed of about 0.5 to 1.5 m/min.

35. An apparatus according to claim 30 in which said chamber is adapted to be maintained at a temperature of  $-25$  to  $-45^{\circ}\text{C}$ .

36. The process of claim 2 wherein the concentrated extract is foamed to an overrun density of between about 0.1 to 0.8 gm/cc.

37. The process of claim 2 wherein the concentrated [506] extract is foamed to an overrun density of between 0.4 to 0.8 gm/cc.

38. The process of claim 2 wherein the frozen foam is vacuum freeze-dried at a pressure of about 150 to 175 microns.

39. The process of claim 3 wherein the frozen foam is vacuum freeze-dried at a pressure of about 150 to 175 microns.

41. A coffee powder according to claim 40 wherein the extract before freeze drying contains about 25% to 60% by weight of soluble coffee solids.

42. A dry coffee powder having a density of about 0.2 to 0.3 gm/cc and comprising a freeze dried particulated foamed extract of roast and ground coffee, said extract containing before freeze drying up to about 60% by weight of soluble coffee solids.

43. A coffee powder according to claim 42 containing about 0.1% to 0.5% by weight of aromatic condensate obtained by stripping roast and ground coffee.

### **Footnotes**

Footnote 1. A continuation (or continuation-in-part, as the examiner has required it to be denominated) of application serial No. 537,679, filed March 28, 1966. Appellants claim the benefit of a Swiss application filed April 2, 1965. The title of the application on appeal is somewhat inaccurate, as the application contains claims to apparatus for drying and dried instant coffee products as well as to a drying method.

Footnote 2. So that consumers may continue to use the same amount of freeze-dried instant coffee per cup as conventional instant coffee without change in the strength of the beverage that they are accustomed to.

Footnote 3. 37 CFR 1.204(c):

When the effective filing date of an applicant is more than three months subsequent to the effective filing date of the patentee, the applicant, before the interference will be declared, shall file two copies of affidavits or declarations by himself, if possible, and by one or more corroborating witnesses, supported by documentary evidence if available, each setting out a factual description of acts and circumstances performed or observed by the affiant, which collectively would prima facie entitle him to an award of priority with respect to the effective filing date of the patent. This showing must be accompanied by an explanation of the basis on which he believes that the facts set fourth would overcome the effective filing date of the patent.

Footnote 4. The examiner and the board did not rely on Pfluger 1963 because the solids content

and foam density ranges of the copied claims were not described in that application. In re Lund, 54 CCPA 1361, 376 F.2d 982, 153 USPQ 625 (1967).

Footnote 5. Peebles U. S. patent No. 2,897,084, issued July 28, 1959, was cited against claims 19 and 20 to show that agglomerating fine dried coffee particles into larger grounds was old in the art. Appellants have acknowledged this to be true, so it is not necessary to discuss Peebles further.

Footnote 6. The solicitor belatedly asserts that the Swiss application is not "for the same invention" as the parent application, insofar as claims 1, 2, and 4 are concerned; he argues that the expression "same invention" in 35 USC 119 should be given the meaning employed by us in the double patenting cases, e.g., In re Vogel, 57 CCPA 920, 422 F.2d 438, 164 USPQ 619 (1970). As we indicated in In re Ziegler, 52 CCPA 1473, 347 F.2d 642, 146 USPQ 76 (1965), the solicitor's reading is too narrow. All § 119 requires is that the foreign application describe and seek protection for "broadly the same invention" as described in the U.S. application claiming its benefit. 52 CCPA at 1481, 347 F.2d at 649, 146 USPQ at 82. The Swiss application has essentially the same disclosure as appellants' parent application and claims broadly the same invention.

Footnote 7. That the final product temperature limitation is not material, as appellants argue, does not matter when the limitation is copied. Immateriality excuses only *failure* to copy a limitation of a patent claim. See Brailsford v. Lavet, 50 CCPA 1367, 318 F.2d 942, 138 USPQ 28 (1963); 37 CFR 1.205(a).

Footnote 8. Appellants do not deny that the features added in claims 7, 12, 13, and 14 are taught in the art, and the record shows them to be known in the prior art.

Footnote 9. Appellants argue in their reply brief that claims 40-43 "were never the subject of an accurate or proper rejection," because the examiner and the board incorrectly grouped them with other claims. As we have indicated, the rejection of claims 40-43 on Pfluger under § 103 was "proper"; appellants do not contend that they could not understand the basis for the rejection because of failure of the PTO to give clear reasons for its action under 35 USC 132, and we find the explanations given by the examiner and board with respect to claims 40-43 to have been legally ample under § 132. Cf. In re Gustafson, 51 CCPA 1358, 331 F.2d 905, 141 USPQ 585 (1964).

### **Concurring/Dissenting Opinion Text**

#### **Concurrence/Dissent By:**

Baldwin, Judge, concurring in part and dissenting in part.

I agree with Judge Miller's treatment of claims 17-20 and 29. Otherwise, I join the majority opinion.

**Concurring/Dissenting Opinion Text**

**Concurrence/Dissent By:**

Miller, Judge, dissenting in part and concurring in part.

I dissent on claim 1. The error of the majority in affirming the rejection stems from a misstatement of the issue. It is not necessary when antedating a reference under 35 USC 102(a) or (e) to establish a prior reduction to practice, constructive or actual, of *all* the subject matter falling within the claims. It is necessary only to establish a reduction to practice of sufficient subject matter to render the claimed invention obvious to one of ordinary skill in the art. In re Spiller, 500 F.2d 1170, 182 USPQ 614 (CCPA 1974). The majority errs, therefore, in seeking a description in appellants' parent and foreign priority applications to support the entire claimed subject matter as though these were the applications in which the claims appear. See In re Ziegler, 52 CCPA 1473, 347 F.2d 642, 146 USPQ 76 (1965). Appellants have clearly shown possession of enough of the invention to antedate Pfluger 1966 by establishing a prior constructive reduction to practice in their parent and foreign applications of specific embodiments disclosing concentrating to 50% and 36% total solids and by a broader disclosure of "25 to 60%."

Although the rejection of claim 1 arises in the context of an attempt to initiate an interference, the rejection is clearly under 35 USC 102(a) or (e) and not under Rule 204(c), 37 CFR 1.204(c). Even if the rejection were under that rule, the substance of the rule's requirement for evidence sufficient to establish a prima facie case for a judgment of priority against Pfluger 1966 would be satisfied by the prior constructive reduction to practice of embodiments within claim 1 in appellants' parent and foreign applications. Hunt v. Treppschuh, 523 F.2d 1386, 187 USPQ 426 (CCPA 1975); Fontijn v. Okamoto, 518 F.2d 610, 186 USPQ 97 (CCPA 1975).

The majority cites In re Gemassmer, 51 CCPA 726, 319 F.2d 539, 138 USPQ 229 (1963), to support its decision on claim 1. It suffices to note that Gemassmer was decided more than a decade before In re Spiller, Hunt v. Treppschuh, and Fontijn v. Okamoto, supra.

I concur in the decision on claim 4 since appellants' parent and foreign applications are silent regarding final product temperature and a secondary heating step and, therefore, fail even as a constructive reduction to practice of the invention of claim 4.

I concur also in the decision on claims 19 and 20, but I do not find it necessary to hold, as the majority implicitly does, that "about 0.6" gm/cc excludes 0.5 gm/cc disclosed in the reference as the upper limit of merely a *preferred* range. Moreover, it is obvious from the reference that the process would work at a higher density than 0.5,

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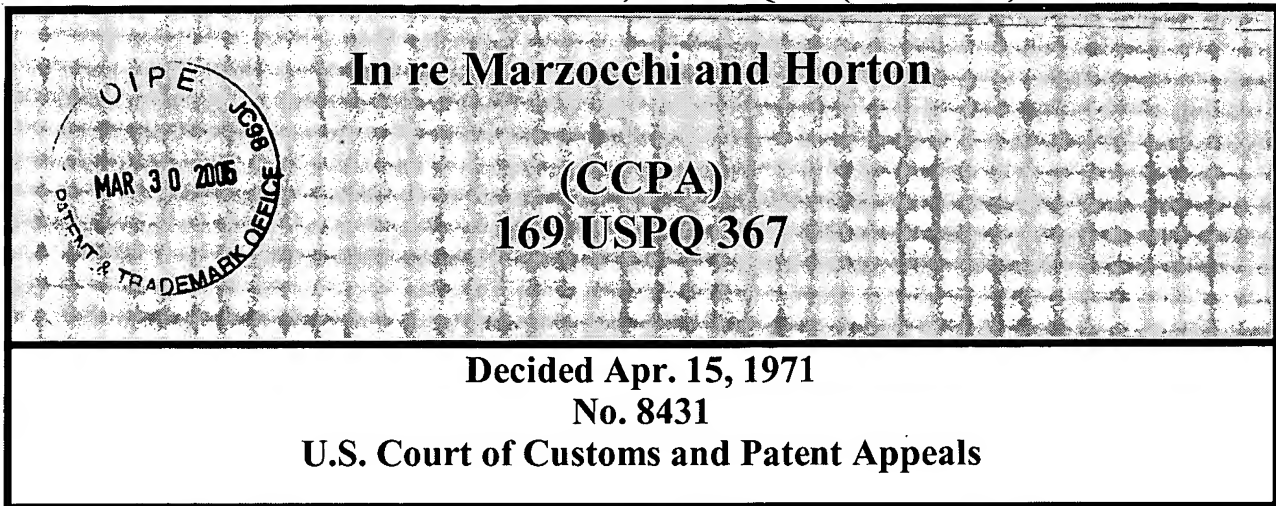
although inferior results might be expected. My concurrence rests on the requirement of claims 19 and 20 of a specific sequence of steps not suggested by the prior art, namely: providing a high

density of about 0.6 to about 0.8 gm/cc, grinding to a fine particle size prior to freeze drying, freeze drying, and finally agglomerating the fine particles into larger particles. This achieves a "highly coloured product of regular particle size." There is no suggestion in the prior art of deliberately grinding to a fine size and then agglomerating to a larger size.

I dissent on claims 17, 18, and 29, because there is at least a prima facie relationship between product and foam densities. The board noted this by stating that "the freeze dried density of the coffee would be inherent in view of the same range of foam overrun density disclosed by Pfluger." Since the foam densities and other conditions disclosed by Pfluger for the process claimed are approximately the same, appellants should be required either to show that the reference does not achieve the same product densities or to establish criticality. Since they have not done so, I would affirm the rejection of claims 17, 18, and 29.

**- End of Case -**

In re Marzocchi and Horton, 169 USPQ 367 (CCPA 1971)



### **Headnotes**

#### **PATENTS**

##### **1. Specification - Sufficiency of disclosure (§ 62.7)**

Recitation of generic term "polyethyleneamine" must be taken as assertion by applicants that all of the "considerable number of compounds" which are included within generic term would, as a class, be operative to produce asserted enhancement of adhesion characteristics; Patent Office has no concern over breadth of term; its only relevant concern should be over truth of such assertion; first paragraph of 35 U.S.C. 112 requires nothing more than objective enablement; how such a teaching is set forth, either by use of illustrative examples or by broad terminology, is of no importance.

##### **2. Pleading and practice in Patent Office - Rejections (§ 54.7)**

##### **Specification - Sufficiency of disclosure (§ 62.7)**

Specification disclosure which contains teaching of manner and process of making and using the invention in terms corresponding in scope to those used in describing and defining subject matter sought to be patented must be taken as in compliance with enabling requirement of first paragraph of 35 U.S.C. 112 unless there is reason to doubt objective truth of statements contained therein which must be relied on for enabling support; assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis; such a rejection can be overcome by suitable proofs indicating that teaching contained

in specification is truly enabling.

### **3. Pleading and practice in Patent Office - Rejections (§ 54.7)**

#### **Specification - Sufficiency of disclosure (§ 62.7)**

In field of chemistry generally, there may be times when well-known unpredictability of chemical reactions will alone be enough to create reasonable doubt as to accuracy of broad statement put forward as enabling support for claim; this will especially be the case where statement is, on its face, contrary to generally accepted scientific principles; most often, additional factors, such as teachings in pertinent references (not necessarily prior art), will be available to substantiate doubts that asserted scope of objective enablement is in fact commensurate with scope of protection sought and to support any demands based thereon for proof; it is incumbent upon Patent Office, whenever, a rejection on this basis is made, to explain why it doubts truth or accuracy of statement in supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with contested statement; otherwise, there would be no need for applicant to support his presumptively accurate disclosure.

#### **Particular patents-Fiber Coatings**

Marzocchi and Horton, Fiber Coatings - Nitrogen Compounds for Improving Adhesion of Vinyl Polymers to Glass, claims 6 and 12 of application allowed; claims 5 and 11 refused.

### **Case History and Disposition:**

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Appeal from Board of Appeals of the Patent Office.

Application for patent of Alfred Marzocchi and Richard C. Horton, Serial No. 470,618, filed July 8, 1965; Patent Office Group 140. From decision rejecting claims 5, 6, 11, and 12, applicants appeal. Affirmed as to claims 5 and 11; reversed as to claims 6 and 12.

#### **Attorneys:**

Herman Hersh and McDougall, Hersh, Scott & Ladd, both of Chicago, Ill.

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(Staelin & Overman, Toledo, Ohio, and George A. Degnan, Washington, D. C., of counsel) for appellants.

S. Wm. Cochran (Fred W. Sherling of counsel) for Commissioner of Patents.

**Judge:**

Before Rich, Almond, Baldwin, and Lane, Associate Judges, and Durfee, Judge, United States Court of Claims, sitting by designation.

**Opinion Text**

**Opinion By:**

Baldwin, Judge.

This is an appeal from the decision of the Patent Office Board of Appeals which affirmed the final rejection of claims 5 and 11 of appellants' application <sup>1</sup> under 35 U.S.C. 103 as unpatentable in view of Werner <sup>2</sup> and of claims 6 and 12 under 35 U.S.C. 112 as being based on an inadequate disclosure. Claims 4 and 10 stand allowed.

**The Invention**

The subject matter of the claims on appeal involves a technique for improving the adhesion characteristics between glass fibers and vinyl polymer resins. Claim 5 is representative and reads as follows:

5. In the combination of glass fibers and a vinyl polymer resin composition present as a coating on the glass fiber surfaces, the improvement which comprises mixing the vinyl polymer resin, prior to coating of the glass fibers, with an amine compound in an amount corresponding to 2-10% by weight of the vinyl polymer resin, and in which the amine compound is monomeric vinyl pyrrolidone.

Claim 11 is drawn to the same concept as claim 5, but defines the invention as "a method of producing glass fibers coated with polyvinyl resin strongly bonded to the glass fiber surfaces." Claims 6 and 12 differ from claims 5 and 11 respectively solely in the recitation of "polyethyleneamine" as the critical "amine compound" additive.

**The Section 103 Rejection**

Claims 5 and 11 were rejected "as obvious in the sense of 35 U.S.C. 103 over Werner." Werner, the sole reference relied upon here, is addressed to the improvement in the bonding relationship between glass and polyvinyl halide resins. The pertinent disclosure is as follows [emphasis added]:

I have found that polyvinyl halide resins may be successfully modified so as to

obtain excellent glass adhesion by employing a mixture of a polyvinyl halide and a *polymer* of N-vinyl pyrrolidone. By employing a mixture containing from 80 to 97% of a polyvinyl halide and from 20 to 3% of a polymer of N-vinyl pyrrolidone, which term includes homopolymers of vinyl pyrrolidone and copolymers with other polymerizable monomers, a composition is obtained having extremely high adhesion to all glass surfaces.

On the basis of this teaching the examiner took the position, accepted by the board, that the claimed use of *monomeric* vinyl pyrrolidone rather than Werner's *polymeric* vinyl pyrrolidone would be obvious to one of ordinary skill in the art since Werner's teaching would indicate to "one skilled in the art \* \* \* that it is the vinyl pyrrolidone moiety that is enhancing the adhesion." It was also suggested by the examiner that since the claims recite no temperature conditions for the coating operation and since monomers polymerize when heated, the claims could possibly cover circumstances wherein the monomer is polymerized during application. The board appears to have accepted this suggestion and to have extended it even further. It stated:

All of Werner's examples specify heating at elevated temperatures (110°C.-130°C., 165°C., 325°F., 350°F.) with and without elevated pressures. Appellants' specification says nothing about retaining the vinyl pyrrolidone in monomeric form, much less anything about "maximizing adhesion" by preventing polymerization. Indeed, the very designation of the vinyl pyrrolidone as a "monomeric" material introduced into a polymer system for the purpose of altering the properties of such system implies subsequent polymerization of the monomer. Appellants' further argument that the monomer has entirely different capabilities and solubilities than the polymer is also unpersuasive.

Appellants' position on appeal in response to these assertions by the examiner and board is largely to stress again the "marked difference between the properties and characteristics of a polymer as compared to a monomer," and to object to the "purely conjectural" assertion that the monomer polymerizes in the coating after it is applied. Additionally, appellants make the following contention:

Even if it were assumed that appellants' monomeric vinyl pyrrolidone is polymerized when present in the polyvinyl chloride coating, there is no teaching or suggestion

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in Werner that the use of monomeric vinyl pyrrolidone has any efficacy whatsoever in compositions of the type disclosed and claimed. The basis suggested by the Patent Office for the rejection is tantamount to the allegation it would be "obvious to try" the monomer. This "test" of obviousness has been frequently repudiated by this court.

The sole issue is, of course, whether the Werner teaching does suggest to a person having ordinary skill in this art that the use of monomeric vinyl pyrrolidone would have the efficacy indicated in the appealed claims. We agree with appellants that whether the monomer

polymerizes is irrelevant, at least in this regard. What is relevant, however, and here determinative, is the examiner's assertion that the Werner teaching would suggest that it is the vinyl pyrrolidone moiety alone and not some other characteristics peculiar to a polymer which is efficacious in producing the desired adhesion enhancement.<sup>3</sup> In the absence of anything to rebut this assertion, which is reasonable on its face, we are constrained to accept it as fact. The inferences which follow from such fact, i.e., that the monomer would possess this same characteristic and that one of ordinary skill would recognize such fact, are inescapable.

It is acknowledged that the above line of reasoning may be viewed as being tantamount to drawing the inference that, to one possessing the ordinary level of skill in this art, it would be "obvious to try" the monomer. Nevertheless, such an *inference of fact may*, at times, be enough to justify drawing the ultimate *conclusion of law* that the claimed subject matter as a whole would have been obvious under section 103. We are satisfied that the circumstances of this case justify an initial conclusion of obviousness. Since the record before us contains nothing to rebut that conclusion, the decision with regard to claims 5 and 11 must be affirmed.

### **The Section 112 Rejection**

Claims 6 and 12, which recite the use of "polyethyleneamine" as the adhesion enhancer, were criticized by the examiner as being based on a disclosure which was not enabling under the first paragraph of 35 U.S.C. 112. The board affirmed his rejection of those claims with the following comment.

The term is obviously generic to a considerable number of compounds varying in the number of ethylene groups, the number of amine groups and the relationship of the polyethylene groups to the amine groups, and accordingly does not provide a reasonable guide for those seeking to improve the adherence of vinyl resins to glass.

We will reverse the board's decision on this rejection since we are unable to find sufficient justification for the holding that appellants' disclosure is not enabling.

[1] Turning specifically to the objections noted by the board as indicated above, it appears that these comments indicate nothing more than a concern over the *breadth* of the disputed term. If we are correct, then the relevance of this concern escapes us. It has never been contended that appellants, when they included the disputed term in their specification, intended only to indicate a single compound. Accepting, therefore, that the term is a generic one, its recitation must be taken as an assertion by appellants that all of the "considerable number of compounds" which are included within the generic term would, as a class, be operative to produce the asserted enhancement of adhesion characteristics. The only relevant concern of the Patent Office under these circumstances should be over the *truth* of any such assertion. The first paragraph of § 112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance.

[2] As a matter of Patent Office practice, then, a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond

in scope to those used in describing and defining the subject matter sought to be patented *must* be taken as in compliance with the enabling requirement of the first paragraph of § 112 *unless* there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. Assuming that sufficient reason for such doubt does exist, a rejection for failure to teach how to make and/or use will be proper on that basis; such a rejection can be overcome by suitable proofs indicating that the teaching contained in the specification is truly enabling.

[3] In the field of chemistry generally, there may be times when the well-known

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unpredictability of chemical reactions will alone be enough to create a reasonable doubt as to the accuracy of a particular broad statement put forward as enabling support for a claim. This will especially be the case where the statement is, on its face, contrary to generally accepted scientific principles. Most often, additional factors, such as the teachings in pertinent references, <sup>4</sup> will be available to substantiate any doubts that the asserted scope of objective enablement is in fact commensurate with the scope of protection sought and to support any demands based thereon for proof. In any event, it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure. Cf. *In re Gazave*, 54 CCPA 1524, 379 F.2d 973, 154 USPQ 92 (1967); *In re Chilowsky*, 43 CCPA 775, 229 F.2d 457, 108 USPQ 321 (1956).

In the present case, the circumstances we see do not support the reasonableness of any doubts which the Patent Office might have had concerning the adequacy of appellants' specification disclosure to support these claims. In fact, those circumstances tend to strengthen rather than weaken appellants' claim to the breadth of protection they seek. In the first place, it has not been asserted by the Patent Office that the chemical properties of known polyethyleneamines vary to such an extent that it would not be expected by one of ordinary skill in this art that any such compound would possess the necessary capability of enhancing adhesion. Additionally, we note that polyethyleneamine is listed in appellants' specification as being only one of a much larger class of amine compounds possessing this necessary characteristic. Finally, we recognize (as did the examiner) the generic nature of appellants' broader concept, i.e., that the desired property of adhesion enhancement stems largely from the amine moiety. It does appear that variation of certain of the secondary factors mentioned by the examiner, such as molecular weight or proportion of ethylene groups, might influence to some degree or even mask the essential "amine" property of the polyethylene amine or its obviously equally essential compatibility with vinyl polymers. However, we see no basis to conclude that the ready avoidance of this result would not be within the level of ordinary skill in this art. Compare *In re Skrivan*, 57 CCPA 1201, 427 F.2d 801, 166 USPQ 85 (1970).

Taking all these circumstances into consideration, we are constrained to conclude that the record before us contains insufficient grounds for questioning the accuracy of appellants' teaching that *any* polyethyleneamine (obviously excepting those whose essential "amine" characteristics and compatibility with vinyl polymers would be masked by the secondary factors mentioned) will function to accomplish the asserted result. It follows that claims 6 and 12 must be held to be supported by a disclosure which is in compliance with the requirements of the first paragraph of 35 U.S.C. 112.

### **Summary**

The decision of the board regarding claims 5 and 11 *affirmed*; that dealing with claims 6 and 12 is *reversed*.

### **Footnotes**

Footnote 1. Serial No. 470,618, filed July 8, 1965, for "Fiber Coatings - Nitrogen Compounds for Improving Adhesion of Vinyl Polymers to Glass" as a continuation-in-part of Serial No. 96,106, filed March 16, 1961.

Footnote 2. U. S. Patent No. 2,853,465, issued September 23, 1958.

Footnote 3. Indeed, the reasonableness of such an assertion is confirmed by the very disclosure contained in appellants' application which indicates that efficacious adhesion enhancers are those "organic nitrogenous compounds which are characterized both by an organic constitution which is compatible with the vinyl polymers and by a polarity expressed in the nitrogen function." As also pointed out by appellants in their brief (about which more will be said later), the nature of the present invention resides in the use of *amine* compounds, broadly, as adhesion enhancers.

Footnote 4. Not necessarily *prior* art references, it should be noted, since the question would be regarding the *accuracy* of a statement in the specification, not whether that statement had been made before.

**- End of Case -**



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